



**Policy Objective: Reduce Diet-Related Disease
by Labeling Gluten as a Major Food Allergen**

CITIZEN PETITION FOR THE LABELING OF GLUTEN AS A MAJOR FOOD ALLERGEN

The Evaluation of this Citizen Petition Including the Public Health Importance of Labeling Gluten as a Major Food Allergen is Requested to Be Conducted Now Through the Lens of President Biden’s Executive Order 13985 (1/20/21) and Executive Order 14091 on “Further Advancing Racial Equity and Support for Underserved Communities Through the Federal Government” (2/16/23)

**An Analysis of How Celiacs Belong to an Underserved Community
of Persons with Disabilities Who Have Systematically Been Denied a
Full Opportunity to Participate in Aspects of Economic, Social, and Civic Life**

Prepared for:

Secretary Xavier Becerra
Department of Health and Human Services

Commissioner Robert M. Califf, M.D.
Food and Drug Administration
Department of Health and Human Services

Prepared By:

Jonathan Bari, Leslie Bari, Jax Bari & Lexi Bari
Celiac Journey, Gluten Free Finds & Bari Consulting Group



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EXECUTIVE SUMMARY: CITIZEN PETITION FOR THE LABELING OF GLUTEN AS A MAJOR FOOD ALLERGEN

Background

Labeling Gluten (Wheat, Barley, Rye and Oats) as a Major Food Allergen on all packaged foods in the U.S., like Gluten is labeled in more than 85 other countries around the world, will better protect 3.3 million Americans with Celiac Disease. Labeling Gluten is in alignment with the conclusions of international food safety authorities and expert committees comprised of scientists, regulators, physicians, clinicians, individuals and risk managers from academia, government and the food industry including:

- 2021 Food and Agriculture Organization of the United Nations/World Health Organization Expert Consultation on Risk Assessment of Food Allergens, which included the FDA's Dr. Lauren Jackson, Chair, and the FDA's Dr. Stefano Luccioli ("2021 FAO/WHO Expert Consultation"). The 2021 FAO/WHO Expert Consultation found, "[b]ased on systematic and thorough assessments which used all three criteria (prevalence, severity and potency), the Committee recommended that the following should be listed as priority allergens: Cereals containing gluten (i.e., wheat and other Triticum species, rye and other Secale species, barley and other Hordeum species and their hybridized strains), crustacea, eggs, fish, milk, peanuts, sesame, specific tree nuts (almond, cashew, hazelnut, pecan, pistachio and walnut)." ¹ (emphasis added)
- 1,576 Comments submitted to the FDA on Labeling Gluten in Summer 2022 including from Dr. Virginia Stallings, a board-certified nutrition pediatrician, Professor of Pediatrics and Director of the Nutrition Center at the Children's Hospital of Philadelphia, Beyond Celiac, National Celiac Association, Gluten Free Watchdog, University of Chicago Center for Celiac Disease, etc. (Docket: FDA-2021-N-0553) ²

Requested Action

Today, Wheat is required to be labeled in the U.S., but Gluten is not. Gluten is found in Wheat, Barley, Rye and most Oats. This Citizen Petition is requesting a long-overdue reckoning by the FDA to better protect more than 3.3 million Americans with Celiac by labeling Gluten (Wheat, Barley, Rye and Oats) as a Major Food Allergen on all packaged foods, just like labeling Gluten is required in more than 85 other countries. Under its existing authority in the Food Allergen Labeling and Consumer Protection Act in statute at 21 U.S.C. § 343(x), we request that the FDA issue a rule to: 1) require that all ingredients with Gluten be listed by name in the ingredient lists of all foods and; 2) add Gluten to the FDA's list of allergens in Sec. 555.250 of its Compliance Policy Guides Manual, "Statement of Policy for Labeling and Preventing Cross-contact of Common Food Allergens" to address both labeling and cross contact issues related to food manufacturing practices.

Advancing Equity Must Be a Central Component of FDA Decision-Making to Evaluate this Citizen Petition and Protect Celiacs, An Underserved Community With a Chronic Disability

The labeling of Gluten as a Major Food Allergen sits at the Intersection of President Biden's Executive Orders on Advancing Equity for Underserved Communities, the White House Conference and National Strategy on Hunger, Health, and Nutrition and human rights.

¹ <http://www.fao.org/3/cb4653en/cb4653en.pdf>

² <https://www.regulations.gov/docket/FDA-2021-N-0553/comments?filter=celiac>

We are respectfully requesting that the evaluation of this Citizen Petition be conducted now through the lens of President Biden’s Executive Order 13985 on “Advancing Racial Equity and Support for Underserved Communities Through the Federal Government” (January 20, 2021) and President Biden’s Executive Order 14091 on “Further Advancing Racial Equity and Support for Underserved Communities Through the Federal Government.” (February 16, 2023):

“Because advancing equity requires a systematic approach to embedding fairness in decision-making processes, executive departments and agencies (agencies) must recognize and work to redress inequities in their policies and programs that serve as barriers to equal opportunity.”³

According to the U.S. Department of Health of Human Services (“HHS”) HHS Equity Action Plan, “advancing equity must be a central component of the decision-making framework that all agency functions are routed through.”⁴

The Celiac community represents an underserved community which shares a particular characteristic including a chronic disability as per the Fourth Circuit Court of Appeals⁵ and a potentially life-threatening and life-debilitating food allergy to eating Gluten with numerous adverse health consequences.

For someone with Celiac Disease, eating, sleeping, thinking, learning and working are major life activities that can be impacted on a daily basis through the ingestion of Gluten, and there are various bodily systems which can be impacted including: gastrointestinal (digestive), nervous (anxiety, ataxia and neuropathy), skeletal, reproductive (infertility) and integumentary.

This Citizen Petition includes a detailed analysis of how Celiacs belong to an underserved community of persons with disabilities who have systematically been denied a full opportunity to participate in aspects of economic, social, and civic life.

Celiac Disease Overview

- Celiac Disease is a potentially life-threatening food allergy, auto-immune disease and digestive disease that impacts at least 3.3 million Americans, greater than 1.0% of the general population.
- Researchers are finding that Celiac Disease prevalence is doubling approximately every 15 years, making it a public health epidemic. Gluten ingestion for people with Celiac can cause anemia, cancer, heart disease, immunological scarring, intestinal damage, malnutrition, etc.
- The only available treatment is strict adherence to a lifelong, Gluten Free diet. There is no rescue medication in the event of accidental ingestion and one cannot outgrow Celiac.
- 44% of people with Celiac Disease who follow a strict Gluten Free diet still get glutened once a month, and “many with celiac disease pay over 40% more in annual healthcare costs.”⁶

³ <https://www.federalregister.gov/documents/2021/01/25/2021-01753/advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government>

⁴ <https://www.hhs.gov/sites/default/files/hhs-equity-action-plan.pdf>

⁵ United States Court of Appeals for the Fourth Circuit, No. 18-1725, Argued: January 29, 2019; Decided: May 31, 2019, See www.celiacjourney.com/williamsburg and <https://www.ca4.uscourts.gov/opinions/181725.P.pdf>

⁶ <https://twitter.com/abast/status/1551780196243603457> and <https://www.beyondceliac.org/>

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I. Introduction to the Citizen Petition

**“When you see something that is not right, not fair, not just, you have to speak up.
You have to say something; you have to do something!”**

-- Congressman John Lewis, The Conscience of the Congress

**“For me, an area of moral clarity is: you’re in front of someone who’s suffering and you
have the tools at your disposal to alleviate that suffering
or even eradicate it, and you act.”**

-- Dr. Paul Farmer⁷

A. Overview

The undersigned respectfully submit this citizen petition pursuant to § 4(d) of the Administrative Procedures Act, 5 U.S.C. § 553(e); 21 U.S.C. §§ 321(n), 343(a), 343(x), and 371 (a); and 21 C.F.R. § 10.30 (“Citizen Petition”). We respectfully request that the Commissioner of the Food and Drug Administration (“FDA”) issue a rule to require that Gluten (Wheat, Barley, Rye and Oats, collectively “Gluten Containing Grains”)⁸ be regulated in a manner similar to a Major Food Allergen under the Food Allergen Labeling and Consumer Protection Act of 2004 (“FALCPA”)⁹ and listed specifically by name (Wheat, Barley, Rye and Oats) in ingredient lists on food products. We are also requesting in this Citizen Petition that the FDA add Gluten to its list of allergens in Sec. 555.250 of its Compliance Policy Guides Manual, “Statement of Policy for Labeling and Preventing Cross-contact of Common Food Allergens,” to address both labeling and cross contact issues related to Gluten in food manufacturing practices.¹⁰

⁷ <https://hms.harvard.edu/news/memorial-paul-farmer>

⁸ Gluten Containing Grains are Wheat, Barley, Rye and most Oats. Wheat is already codified as a Major Food Allergen in the U.S. as per the Food Allergen Labeling and Consumer Protection Act of 2004. As such, the focus of this Citizen Petition is on adding Barley, Rye and Oats to the list of Major Food Allergens as the other sources of Gluten. While Oats are naturally Gluten Free, cross contamination of Oats with Gluten is for all intents and purposes inevitable. See Section IV.G. in this Citizen Petition entitled, “Oats Must Be Included by the FDA as a Gluten Containing Grain and Thus Declared on All Food Packages.”

⁹ FALCPA amended the Federal Food, Drug, and Cosmetic Act (“FD&C Act”) as follows: Section 201 (qq) was added to define the term “major food allergen.” The term means any of the following foods, or a food ingredient that contains protein derived from any of the following foods: milk; eggs; fish; crustacean shellfish; tree nuts; wheat; peanuts; and soybeans. Section 403(w) was added to address the labeling of foods that contain a major food allergen. Effective January 1, 2006, all food labels must clearly state if food products contain any ingredients that contain protein derived from the eight major allergenic foods. See Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) (Public Law 108-282, Title II). In April 2021, the Food Allergy Safety, Treatment, Education, and Research Act of 2021 (FASTER Act) amended section 201(qq) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) to add sesame to the definition of “major food allergen.” This amendment applies to “any food that is introduced or delivered for introduction into interstate commerce on or after January 1, 2023” (Public Law 117-11).” <https://www.fda.gov/media/157637/download>

¹⁰ On May 16, 2023, the FDA announced the availability of a draft Compliance Policy Guide (“CPG”) entitled Sec 555.250: Major Food Allergen Labeling and Cross-contact

Celiac Disease is a potentially life-threatening and life-debilitating food allergy,¹¹ auto-immune disease,¹² and digestive disease¹³ that is triggered by eating Gluten, a protein found in Wheat, Barley, Rye and most Oats. The only treatment for Celiac Disease is a strict, lifelong Gluten Free diet. There is no rescue medication in the event of accidental Gluten ingestion, and one cannot outgrow Celiac. Beyond Celiac reported that 44% of people with Celiac Disease who follow a strict Gluten Free diet still get glutened once a month.¹⁴

This Citizen Petition is a response to the “White House Challenge to End Hunger and Build Healthy Communities.”¹⁵ Labeling Gluten will reduce the treatment burden, food insecurity and diet-related disease for those with Celiac Disease, a potentially life-threatening and life-debilitating food allergy and auto-immune disease, from adverse health effects that can arise following Gluten ingestion.

Labeling Gluten comports with the “White House Conference Pillar #2, Integrate nutrition and health: Prioritize the role of nutrition and food security in overall health, including disease prevention and management, and ensure that our health care system addresses the nutrition needs of all people.”¹⁶

In response to the FDA’s “Evaluating the Public Health Importance of Food Allergens Other Than the Major Food Allergens Listed in the Federal Food, Drug, and Cosmetic Act: Guidance for FDA Staff and Stakeholders – Draft Guidance,” Docket: FDA-2021-N-0553, April 19, 2022 (“FDA’s Draft Guidance”),¹⁷ there were 1,903 public comments¹⁸ submitted to the FDA in 2022. Of the 1,903 comments, 1,576 comments mentioned Celiac and/or Gluten as a food allergen (82.8% of all comments submitted).¹⁹ There was a common theme among the 1,576 comments: label Gluten on all packaged foods in the U.S. to provide better consumer protection for the Celiac community to whom ingesting Gluten is tantamount to eating poison.

(<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cpg-sec-555250-draft-major-food-allergen-labeling-and-cross-contact>). “The draft guidance, when finalized, will replace existing guidance for FDA staff on FDA’s enforcement policy regarding major food allergen labeling and cross-contact.” (<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cpg-sec-555250-statement-policy-labeling-and-preventing-cross-contact-common-food-allergens>). The requested action in this Citizen Petition that the FDA add Gluten to its list of allergens in Sec. 555.250 of its Compliance Policy Guides Manual extends to the new Sec 555.250: Major Food Allergen Labeling and Cross-contact which will replace the existing CPG 555.250 for FDA staff.

¹¹ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4241964/pdf/nihms247178.pdf> (pages 5, 11-12); and <https://www.fda.gov/media/157637/download> (page 10)

¹² <https://grants.nih.gov/grants/guide/notice-files/not-ai-22-004.html#>

¹³ <https://www.niddk.nih.gov/health-information/digestive-diseases>

¹⁴ <https://twitter.com/abast/status/1551780196243603457>

¹⁵ <https://www.whitehouse.gov/briefing-room/statements-releases/2023/03/24/fact-sheet-biden-harris-administration-launches-the-white-house-challenge-to-end-hunger-and-build-healthy-communities-announces-new-public-private-sector-actions-to-continue-momentum-from-hist/>

¹⁶ <https://www.whitehouse.gov/wp-content/uploads/2022/09/White-House-National-Strategy-on-Hunger-Nutrition-and-Health-FINAL.pdf>

¹⁷ <https://www.fda.gov/media/157637/download>

¹⁸ <https://www.regulations.gov/docket/FDA-2021-N-0553/comments>

¹⁹ <https://www.regulations.gov/docket/FDA-2021-N-0553/comments?filter=celiac>

One of the 1,576 comments came from Dr. Virginia Stallings, Professor of Pediatrics and Director of the Nutrition Center at the Children’s Hospital of Philadelphia (“CHOP”), in which Dr. Stallings called for Gluten to be labeled on all packaged foods in the United States (see Citizen Petition Exhibit 1).²⁰ Dr. Stallings is one of the world’s foremost experts on food allergens, and she served as the Editor and Chair of the National Academies of Sciences, Engineering, and Medicine, Committee on Food Allergies which published the seminal work: “Finding a Path to Safety in Food Allergy: Assessment of the Global Burden, Causes, Prevention, Management and Public Policy” (“Finding a Path”).²¹ For more information, see Section IV.F. in this Citizen Petition, “Dr. Virginia Stallings, Professor of Pediatrics and Director of the Nutrition Center at the Children’s Hospital of Philadelphia Has Called for Gluten to Be Labeled.”

“My strong recommendation is that gluten be labeled on all packaged foods in the United States, in accordance with the 2021 FAO/WHO Expert Consultation, just like it is in more than 85 countries around the world.”²²

-- Dr. Virginia Stallings

Celiac Journey is a patient advocacy organization that was started by Jon and Leslie Bari after their son Jax Bari was diagnosed with Celiac Disease in August 2018, right before he started Kindergarten. As Jax learned to read, he started with fairy tales and food labels. Celiac Journey conducts research and publishes articles pertaining to Celiac Disease and our two primary goals (in no order of importance):

1. Increase government funding to find a cure and more treatment options, other than a strict Gluten Free diet for life (over the past decade, only about \$3 million has been annually appropriated by the NIH to Celiac research -- only about \$1 per American with Celiac, per year, and that is not nearly enough)²³; and
2. Declare Gluten as a Major Food Allergen and require that Gluten be labeled on all packaged foods in the U.S., just like it is 85+ countries worldwide, including across Europe and in Canada.²⁴

²⁰ https://downloads.regulations.gov/FDA-2021-N-0553-1169/attachment_1.pdf

²¹ https://www.ncbi.nlm.nih.gov/books/NBK435943/pdf/Bookshelf_NBK435943.pdf

As the Food Allergy Committee which Dr. Stallings chaired found, “The 1999 CAC [Codex Alimentarius Commission] priority list included milk, egg, fish, crustacean shellfish, peanut, soybean, tree nuts, cereal grain sources of gluten, and sulfites. Several of these items were added because the FAO [Food and Agriculture Organization of the United Nations] Technical Consultation also considered celiac disease, intolerances, and sensitivity reactions in addition to immunoglobulin E (IgE)-mediated food allergies in its deliberations. **For example, gluten was included because of its association with celiac disease.**” (page 284)

“In the United States, the priority list of allergenic foods was established by the Congress with the passage of the Food Allergen Labeling and Consumer Protection Act, 67 [‘For an analysis on Food Allergen Labeling and Consumer Protection Act see Derr (When Food Is Poison), 2006.’] (FALCPA) of 2004. The FALCPA list mirrored the 1999 CAC list except that the FALCPA list did not address celiac disease and therefore did not recognize cereal sources of gluten as major allergenic foods.” (page 286)

²² https://downloads.regulations.gov/FDA-2021-N-0553-1169/attachment_1.pdf

²³ www.celiacjourney.com/briefing

²⁴ www.celiacjourney.com/labels

In October 2022, Jax, age 10, met President Biden and pleaded for his help on labeling Gluten. Jax shared with the President that,

“Eating without fear is our hope! Food insecurity happens every day for Celiacs because of the constant threat of cross contact with Gluten, 80% of foods have Gluten in them, the high price of Gluten Free food, the limited availability of Gluten Free food, and moreover Gluten is not required to be labeled on packaged foods in the US like it is in Canada and across Europe.”²⁵

Our family’s story represents just one story from the millions of Americans who live with and/or care for someone with Celiac Disease who require a strict Gluten Free diet with every bite, every day.

On the cover of this Citizen Petition is a photo of Jax after he accidentally got “glutened”²⁶ and became violently sick on April 1, 2023 in Denver, Colorado; Jax was incapacitated on the bathroom floor and in bed for two days following his ingestion of a trace amount of Gluten.²⁷ While many of the physical symptoms abated in a week, the anxiety of that glutening has continued every day.

Jax is one of the many faces of Celiac Disease who can speak to the public health importance of food allergens other than the Major Food Allergens, and specifically, why we need Gluten to be declared a Major Food Allergen and labeled on all packaged foods in the U.S. in order to adequately protect him and millions of others similarly situated.²⁸

B. Requested Action

Today, Wheat is required to be labeled in the U.S., but Gluten is not. Gluten is found in Wheat, Barley, Rye and most Oats. This Citizen Petition is requesting a long-overdue reckoning by the FDA to better protect more than 3.3 million Americans with Celiac Disease by labeling Gluten (Wheat, Barley, Rye and Oats²⁹) as a Major Food Allergen on all packaged foods, just like labeling Gluten is done in more than 85 other countries.

Labeling Gluten on all packaged foods in the U.S. is in alignment with the conclusions of the 2021 Food and Agriculture Organization of the United Nations (“FAO”)/World Health

²⁵ www.celiacjourney.com/abcnews

²⁶ Glutened means ingesting Gluten.

²⁷ <https://www.instagram.com/p/CqnYV7lrRR4/>

²⁸ This Citizen Petition and the Bari Comments to the FDA’s Draft Guidance (FDA Comment ID: FDA-2021-N-0553-1584, FDA Tracking Number l6w-qe9m-4tjy) are intentionally very detailed in order to aggregate a lot of seemingly disparate, yet related, historical, legislative, regulatory, legal, medical and moreover patient advocacy perspective information. This Citizen Petition and the Bari Comments are designed to ensure that the record is very clear since the FDA’s historical actions and FDA’s Draft Guidance from 2022 suggest that time has had a way of blurring perspective for the FDA when it comes to the Food Allergen Labeling and Consumer Protection Act of 2004 and especially the consumer protection needs of those with Non-IgE-Mediated food allergy.

²⁹ While Oats are naturally Gluten Free, cross contamination of Oats with Gluten is for all intents and purposes inevitable. See Section IV.G. in this Citizen Petition entitled, “Oats Must Be Included by the FDA as a Gluten Containing Grain and Thus Declared on All Food Packages.”

Organization (“WHO”) Expert Consultation, which was chaired by the FDA’s Dr. Lauren Jackson³⁰ (“2021 FAO/WHO Expert Consultation”). The 2021 FAO/WHO Expert Consultation “determined that **only foods or ingredients that cause immune-mediated hypersensitivities such as IgE-mediated food allergies and coeliac³¹ [Celiac] disease should be included on the list of foods and ingredients included in section 4.2.1.4 of the GSLPF [General Standard for the Labelling of Prepacked Foods]**,”³² and that the **GSLPF list includes Gluten**. (emphasis added) See Citizen Petition Exhibit 2. The 2021 FAO/WHO Expert Consultation “identified **prevalence** of the immune-mediated hypersensitivity to a specific food, **severity** (i.e. proportion of severe objective reactions to a food/ingredient *such as anaphylaxis*), and the **potency** of food/ingredient (i.e. the amount of the food/ingredient required to cause objective symptoms) as the three key criteria that should be used to establish the priority allergen list.”³³

Labeling Gluten on all packaged foods in the U.S. is also in alignment with the conclusions of the Joint Food and Agriculture Organization of the United Nations/World Health Organization Expert Committee on Food Additives (“1999 FAO/WHO Expert Consultation” or “1999 Codex Criteria”)³⁴ See Citizen Petition Exhibit 3.

Under its authority in FALCPA, in statute at 21 U.S.C. § 343(x),³⁵ we request that the FDA issue a rule to: 1) require that all ingredients with Gluten-Containing Grains³⁶ be listed by name in the ingredient lists of all foods and; 2) add Gluten to the FDA’s list of allergens in Sec. 555.250 of its Compliance Policy Guides Manual, “Statement of Policy for Labeling and Preventing Cross-contact of Common Food Allergens” to address both labeling and cross contact issues related to food manufacturing practices.³⁷ Please also see Section II in this Citizen Petition entitled, “Statement of Legal Grounds.”

³⁰ <http://www.fao.org/3/cb4653en/cb4653en.pdf>

³¹ “Coeliac” is the Greek spelling of Celiac which is used in some parts of the world.

³² <http://www.fao.org/3/cb4653en/cb4653en.pdf>

³³ <http://www.fao.org/3/cb4653en/cb4653en.pdf>

³⁴ https://apps.who.int/iris/bitstream/handle/10665/42378/WHO_TRS_896.pdf (Annex 4, pages 124-128)

³⁵ That section provides: “(x) Nonmajor food allergen labeling requirements: Notwithstanding subsection (g), (i), or (k) of this section, or any other law, a spice, flavoring, coloring, or incidental additive that is, or that bears or contains, a food allergen (other than a major food allergen), as determined by the Secretary by regulation, shall be disclosed in a manner specified by the Secretary by regulation.”

³⁶ The term “Gluten-Containing Grains” means any one of the following grains (or any crossbred hybrid thereof): Wheat, including any species belonging to the genus *Triticum*; Rye, including any species belonging to the genus *Secale*; Barley, including any species belonging to the genus *Hordeum*; and Oats, including any species belonging to the genus *Avena sativa*. Wheat is already codified as a Major Food Allergen in the U.S. as per the Food Allergen Labeling and Consumer Protection Act of 2004. As such, the focus of this Citizen Petition is on adding Barley, Rye and Oats to the list of Major Food Allergens as the other sources of Gluten.

³⁷ While the requested action under this Citizen Petition is for the FDA to regulate Gluten in a manner similar to a Major Food Allergen under the FALCPA (and that this is the preferred implementation thereof), this Citizen Petition is asking that the FDA use any labeling scheme available under its existing statutory and discretionary authority to require that Gluten be declared on all packaged foods in the United States.

These two common-sense measures would help to better protect millions of Americans including:

- 3.3+ million American Celiacs,³⁸ plus their loved ones, parents and caretakers; an
- an additional estimated 20+ million Americans who have Non-Celiac Gluten Sensitivity (“NCGS”);³⁹ and
- those who have an IgE-Mediated food allergy to Rye, Barley or Oats (see Section XIII in this Citizen Petition entitled “IgE-Mediated Food Allergies to Gluten from Rye, Barley & Oats”; and
- other Americans who follow a medically required Gluten Free diet.^{40 41}

We further request that the FDA issue public educational materials directed at restaurants and food providers to raise awareness that Gluten and Gluten-based ingredients can cause severe allergic reactions, and that the agency request that the model Food Code be modified to reflect the allergenic risks of Gluten so that restaurant workers are aware of this risk to consumers and could advise Gluten-allergic consumers which foods to avoid.

Labeling Gluten will reduce diet-related disease for millions of Americans from food protein induced sickness including potentially life-threatening and life-debilitating adverse health effects such as damage to intestinal lining, malnutrition, permanent immunological scarring, iron

³⁸ <https://grants.nih.gov/grants/guide/notice-files/NOT-AI-22-004.html>

³⁹ <https://www.verywellhealth.com/how-many-people-have-gluten-sensitivity-562965>

⁴⁰ According to the National Celiac Association, there is a demand for Gluten Free food from families with children with an Autism Spectrum Disorder. There are a number of other conditions, particularly gastric and autoimmune conditions, where a Gluten Free diet may diminish symptoms. See <https://nationalceliac.org/wp-content/uploads/2018/04/GF-Food-Assistance-GuideGeneralv3.pdf> , and <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7915454/>

⁴¹ According to Dr. Amanda Muir from the Children’s Hospital of Philadelphia, “Eosinophilic esophagitis, or EoE, is a chronic allergic disease that affects pediatric patients and adults alike. In the setting of exposure to foods that are ubiquitous in the American diet, most commonly milk and gluten, an inflammatory process occurs in the esophagus leading to esophageal damage and narrowing. Celiac Disease is an autoimmune disorder in which exposure to gluten containing foods, causes, ‘face potentially life-threatening illnesses if they eat gluten, typically found in breads, cakes, cereals, pastas, and many other foods... There is no cure for celiac disease and the only way to manage the disease is to avoid eating gluten.’

[<https://www.fda.gov/consumers/consumer-updates/gluten-free-means-what-it-says>] Taken together, these two entities, Celiac Disease and EoE represent non-IgE mediated food allergies that would greatly benefit from specific gluten labeling.” FDA Comment ID: FDA-2021-N-0553-1587, FDA Tracking Number l6w-qnl1-geu8, https://downloads.regulations.gov/FDA-2021-N-0553-1587/attachment_1.pdf

deficiency anemia, diarrhea, vomiting, migraines, osteoporosis, additional autoimmune diseases, heart disease, intestinal cancers, and anaphylaxis.^{42 43}

The term “Gluten” means the proteins that occur in Gluten Containing Grains; and cause adverse health effects in persons with food hypersensitivities including Non-IgE-Mediated food allergy (Celiac Disease), IgE-Mediated food allergy, or other food intolerances related thereto.

C. Environmental Impact

The action requested here is subject to a categorical exclusion under 21 C.F.R. §§ 25.30(k) and 25.32(p), and therefore does not require the preparation of an environmental assessment. In any event, the undersigned do not believe that the actions requested in this petition would have any environmental impact.

D. Economic Impact

The Commissioner of the FDA has not requested a statement of the economic impact of the requested action with the labeling of Gluten as a Major Food Allergen, and therefore such a statement is not presented.⁴⁴ That said, the labeling of Sesame as the 9th Major Food Allergen serves as an instructive reference point and benchmark in terms of the economic impact for labeling Gluten as a Major Food Allergen. See Section XIV in this Citizen Petition entitled, “Economic Impact - Cost Estimates with Naming Gluten as a Major Food Allergen.”

⁴² https://downloads.regulations.gov/FDA-2021-N-0553-1169/attachment_1.pdf ;
<https://www.congress.gov/event/117th-congress/senate-event/LC65823/text?s=1&r=42> ;
<https://celiac.org/about-celiac-disease/what-is-celiac-disease/> ;
<https://celiac.org/about-the-foundation/featured-news/2019/02/chronic-inflammation-permanently-alters-immune-cells-in-celiac-patients/> ;
<https://www.niddk.nih.gov/health-information/digestive-diseases/celiac-disease/symptoms-causes> ; and
<https://www.beyondceliac.org/celiac-disease/symptoms/#>

⁴³ See Section XII. in this Citizen Petition entitled, “IgE-Mediated Food Allergies to Gluten from Rye, Barley & Oats.”

⁴⁴ “D. Economic Impact: The following information is to be submitted only when requested by the Commissioner following review of the petition: A statement of the effect of requested action on: (1) Cost (and price) increases to industry, government, and consumers; (2) productivity of wage earners, businesses, or government; (3) competition; (4) supplies of important materials, products, or services; (5) employment; and (6) energy supply or demand.)” Source: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?FR=10.30>

E. Summary of Recent Meetings with the Biden-Harris Administration on Labeling of Gluten as a Major Food Allergen



Jax Bari, Age 9, Talked Food Policy with President Biden and Asked for Help: Reduce Diet-Related Disease by Labeling Gluten as a Major Food Allergen, October 20, 2022

“I admire your courage and the incredible work you’ve done to help the millions of Americans like you who live with Celiac disease. The story about you on the news was terrific, and I am so impressed that you met with Members of the United States Congress to talk about ways to further improve the lives of people with Celiac disease... Young Americans like you are the future of our Nation. When you make your voice heard, adults listen. I look forward to seeing where your future takes you and the positive changes you inspire for people with Celiac disease.”⁴⁵

-- Letter from President Joe Biden to Jax Bari, August 17, 2021

The petitioners who filed this Citizen Petition have held various meetings with the Biden-Harris Administration leading up to the White House Conference on Hunger, Nutrition, and Health on September 28, 2022⁴⁶ (“White House Conference”) and thereafter, Jax meeting President Joe Biden on October 20, 2022 and asking the President to help better protect Celiacs by labeling Gluten:⁴⁷

- May 7, 2022 - Met with Dr. Sandi Ford, Special Assistant to the President of the United States for Public Health and Science, asked the President to help better protect Celiacs by labeling Gluten as a Major Food Allergen.⁴⁸

⁴⁵ www.celiacjourney.com/biden

⁴⁶ www.celiacjourney.com/takeaways

⁴⁷ www.celiacjourney.com/biden2

⁴⁸ <https://www.instagram.com/p/CdQs26Kr2MC/>

- June 7, 2022 - Participated in the White House Conference on Hunger, Nutrition, and Health Listening Session and provided spoken comments in the Breakout Room for Pillar 2, “Integrate nutrition and health: Prioritize the role of nutrition and food security in overall health, including disease prevention and management, and ensure that our health care system addresses the nutrition needs of all people.”⁴⁹
- July 15, 2022 - Submitted written comments to inform the White House Conference on Hunger, Nutrition, and Health.
- September 24, 2022 – Submitted Jax Bari’s capsule video to support the White House Conference.⁵⁰ Please watch this [video](#) to hear directly from Jax in which he shared his lived experience and pleaded for help from the President to declare Gluten as a Major Food Allergen on all packaged foods in the U.S.



- September 25, 2022 – Informed the White House about avoiding euphemisms (i.e., “people who are differently-abled”) when referring to people with disabilities, and helped to change the National Strategy on languaging disabilities.⁵¹
- September 28, 2022 – Attended the White House Conference on Hunger, Nutrition and Health and met with various officials including Ambassador Susan Rice; FDA Commissioner Robert M. Califf, M.D.; Senator Cory Booker; Senator Debbie Stabenow; Rep. Rosa DeLauro; Rep. Jim McGovern; Rep. Mary Gay Scanlon; Chef José Andrés, etc.⁵² See Citizen Petition Exhibit 4.
- October 20, 2022 – Met with President Joe Biden and asked the President to help better protect Celiacs by labeling Gluten as a Major Food Allergen.⁵³

⁴⁹ <https://health.gov/our-work/nutrition-physical-activity/white-house-conference-hunger-nutrition-and-health/conference-details>

⁵⁰ <https://whconfhungerhealth.capsule.video/v/ojdDpea388a6>

⁵¹ www.celiacjourney.com/ada2

⁵² www.celiacjourney.com/takeaways

⁵³ www.celiacjourney.com/biden2 and www.celiacjourney.com/abcnews2

- November 10, 2022 – Met with staff from the White House Domestic Policy Council at the White House^{54 55}
- December 6, 2022 - Met with senior FDA leadership including Dr. Susan Mayne, FDA’s Director, Center for Food Safety and Applied Nutrition (CFSAN); Dr. Claudine Kavanaugh, FDA’s Director, Office of Nutrition and Food Labeling (ONFL); Dr. Pat Hansen, FDA’s Deputy Director, Office of Nutrition and Food Labeling; Dr. Stefano Luccioli, FDA’s Acting CFSAN Chief Medical Officer and Allergen Coordinator.⁵⁶
- April 12, 2023 – Met with the White House Domestic Policy Council staff to provide updates on our advocacy meetings and public policy requests ahead of Celiac Disease Awareness Month in May.
- April 17, 2023 - Met with Senior Staff in the Immediate Office of HHS Secretary Xavier Becerra.⁵⁷

F. Labeling Gluten as a Major Food Allergen is a Public Health Problem Long Overdue for Robust Consumer Protection Action

We submit this Citizen Petition to underscore our concern that the FDA has not been sufficiently prioritizing a public health problem long overdue for robust action: reducing diet-related disease by requiring the labeling of Gluten as a Major Food Allergen on all packaged foods. We respectfully call on the leadership of President Biden, Secretary Xavier Becerra, Commissioner Robert Califf, James “Jim” Jones, Deputy Commissioner for Human Foods,⁵⁸ and Donald A. Prater, Acting Director of the Center for Food Safety and Applied Nutrition, to address this critical consumer protection food safety issue with the urgency it requires.

G. Advancing Equity Must Be a Central Component of HHS & FDA Decision-Making to Evaluate this Citizen Petition and Protect Celiacs, An Underserved Community With a Chronic Disability

We are respectfully requesting that the evaluation of this Citizen Petition be conducted now through the lens of President Biden’s Executive Order 13985 on “Advancing Racial Equity and Support for Underserved Communities Through the Federal Government” (January 20, 2021)⁵⁹ and President Biden’s Executive Order 14091 on “Further Advancing Racial Equity and Support for Underserved Communities Through the Federal Government.” (February 16, 2023)⁶⁰:

“Because advancing equity requires a systematic approach to embedding fairness in decision-making processes, executive departments and agencies (agencies) must

⁵⁴ <https://www.celiacjourney.com/whitehouse>

⁵⁵ <https://tinyurl.com/CeliacJourney>

⁵⁶ <https://www.celiacjourney.com/fda2>

⁵⁷ <https://www.celiacjourney.com/hhsreadout>

⁵⁸ Mr. Jones is scheduled to start work at the FDA on September 24, 2023.

<https://www.fda.gov/news-events/press-announcements/fda-names-first-deputy-commissioner-proposed-unified-human-foods-program>

⁵⁹ <https://www.federalregister.gov/documents/2021/01/25/2021-01753/advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government>

⁶⁰ <https://www.federalregister.gov/documents/2023/02/22/2023-03779/further-advancing-racial-equity-and-support-for-underserved-communities-through-the-federal>

recognize and work to redress inequities in their policies and programs that serve as barriers to equal opportunity.”⁶¹

According to the HHS Equity Action Plan, “**advancing equity must be a central component of the decision-making framework that all agency functions are routed through.**”⁶²

The Celiac community represents an underserved community which shares a particular characteristic including a chronic disability as per the Fourth Circuit Court of Appeals⁶³ and a potentially life-threatening and life-debilitating food allergy to eating Gluten with numerous adverse health consequences.

For someone with Celiac Disease, eating, sleeping, thinking, learning and working are major life activities that can be impacted on a daily basis, and there are various bodily systems which can be impacted including: gastrointestinal (digestive), nervous (anxiety, ataxia and neuropathy), skeletal, reproductive (infertility) and integumentary.

Eating out of the house is very challenging for Celiacs, and this impacts their quality of life on a daily basis. Given that so many of life’s daily activities involve food, that food insecurity happens every day for Celiacs, that so many major life activities can be impacted on a daily basis. and that Gluten is not required to be labeled, Celiacs have been systematically denied a full opportunity to participate in aspects of economic, social, and civic life.

One foundational way to help mitigate accidental glutenings and change societal views that Celiac is as serious as a peanut allergy, for example, is to require that Gluten be labeled as a Major Food Allergen.

Please see Section V. in this Citizen Petition entitled, “President Biden’s Executive Order 13985 On Advancing Racial Equity and Support for Underserved Communities Through the Federal Government & President Biden’s Executive Order 14091: Further Advancing Racial Equity and Support for Underserved Communities Through the Federal Government.”

⁶¹ <https://www.federalregister.gov/documents/2021/01/25/2021-01753/advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government>

⁶² <https://www.hhs.gov/sites/default/files/hhs-equity-action-plan.pdf>

⁶³ In May 2019, in a case involving the disability rights of a child who has a severe allergy to Gluten, the U.S. Fourth Circuit Court of Appeals cited that “[t]he ADA [Americans with Disabilities Act] defines a ‘disability’ in pertinent part as ‘a physical or mental impairment that substantially limits one or more major life activities’” and that “[e]ating is a major life activity.” J.D., by his father and next friend, Brian Doherty, Plaintiff-Appellant v. Colonial Williamsburg Foundation, Defendant-Appellee, National Disability Rights Network; Disability Law Center for Virginia; Scott Hayes; Virginia Food Allergy Advocates, Amici Supporting Appellant. Vacated and Remanded -Appeal from the United States District Court for the Eastern District of Virginia, at Newport News. Rebecca Beach Smith, District Judge. (4:17-cv-00101-RBS-RJK); United States Court of Appeals for the Fourth Circuit, No. 18-1725, Argued: January 29, 2019; Decided: May 31, 2019, See www.celiacjourney.com/williamsburg and https://e283a7ed-372c-4d14-b65c-6fe40bfad779.usrfiles.com/ugd/e283a7_82b2da0c6e2d40ee9f55e3e57ef820a4.pdf

H. The FDA’s Draft Guidance – “Evaluating the Public Health Importance of Food Allergens Other Than the Major Food Allergens Listed in the Federal Food, Drug, and Cosmetic Act: Guidance for FDA Staff and Stakeholders, April 19, 2022” Represents a Biased and Unfair Decision-Making Framework

According to the 2022 Reagan-Udall Foundation for the Food and Drug Administration, Food and nutrition-related risks affect everyone. FDA is responsible for overseeing the safety of 78% of the U.S. human food supply⁶⁴ and all animal feed, in addition to promoting good nutrition.”⁶⁵ However, food-related risks disproportionately impact 3.3 million American Celiacs and their loved ones when the only available treatment is a strict Gluten Free diet for life, there is no rescue medicine available in the event of accidental ingestion, and Gluten is not required to be labeled on all food products.

Based on detailed research, analysis and the Celiac community’s lived experiences with a chronic disability (as per the Americans with Disabilities Act), we believe that advancing equity must be a central component of the decision-making framework that all FDA functions are routed through, including with “Evaluating the Public Health Importance of Food Allergens Other Than the Major Food Allergens Listed in the Federal Food, Drug, and Cosmetic Act: Guidance for FDA Staff and Stakeholders – Draft Guidance”, Docket: FDA-2021-N-0553, April 19, 2022 (“FDA’s Draft Guidance”).⁶⁶

However, with respect to the Celiac Disease community, which has been historically underserved and marginalized by the Federal government (i.e., underfunding medical research for Celiac Disease,⁶⁷ labeling Gluten only with a voluntary scheme,⁶⁸ disqualifying Celiacs from service in the military,⁶⁹ excluding Celiac Disease from the CDC’s Index of Diseases & Conditions,⁷⁰ etc.), the FDA’s Draft Guidance presented an inequitable evaluation framework.

The FDA’s Draft Guidance perpetuated flawed scientific, governmental, and societal biases including:

1. A Gluten Free diet is all that is needed to treat Celiac Disease, as opposed to all that has ever been historically available to treat Celiac Disease.

⁶⁴ <https://www.fda.gov/about-fda/fda-basics/fact-sheet-fda-glance>

⁶⁵ “Operational Evaluation of the FDA’s Human Foods Program: A Report of the Human Foods Independent Expert Panel.” Henney, et. al; 2022, Reagan-Udall Foundation for the Food and Drug Administration, December 2022, <https://reaganudall.org/sites/default/files/2022-12/Human%20Foods%20Program%20Independent%20Expert%20Panel%20Final%20Report%20120622.pdf>

⁶⁶ <https://www.fda.gov/media/157637/download>

⁶⁷ <https://www.celiacjourney.com/briefing>

⁶⁸ <https://www.celiacjourney.com/falcpa>

⁶⁹ U.S. Department of Defense, DoD Instruction 6130.03, Medical Standards for Appointment, Enlistment, or Induction into the Military Services, Section 5.12.c.(3), May 6, 2018, <https://www.esd.whs.mil/DD/>; and https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/613003_vol1.PDF?ver=7fhqacc0jGX_R9_1iexudA%3d%3d

⁷⁰ <https://www.cdc.gov/az/f.html>

2. With respect to labeling food products in the United States, the voluntary Gluten Free labeling scheme⁷¹ sufficiently protects consumers who are on medically required and very restrictive Gluten Free diets, as opposed to all that has ever been historically utilized labeling-wise.
3. Othering the consumer protection needs for Celiacs in the United States with not evaluating the public health importance of Gluten as a food allergen because this Non-IgE-Mediated food allergy is not capable of triggering anaphylaxis and being *immediately* life-threatening, while seemingly ignoring that Celiacs face potentially life-threatening and severe adverse health effects⁷² that can arise through Gluten ingestion, including by way of example and not limitation: anemia, cancer, heart disease, immunological scarring, intestinal damage, malnutrition, etc.

In total, there were 1,903 public comments submitted to the FDA on the FDA's Draft Guidance,⁷³ and of those, 1,576 comments mentioned Celiac and/or Gluten as a food allergen (82.8% of all comments submitted).⁷⁴ There was a common theme among the 1,576 comments – label Gluten to better protect the Celiac community. While the comment period closed on August 16, 2022, the FDA has not provided any updates or responses.

When we met with the FDA on December 6, 2022 and asked for an update including whether they were going to revise the FDA's Draft Guidance to include the evaluation of the public health importance of labeling Gluten as a Major Food Allergen, the FDA offered no comment and no timetable, other than to seemingly say because of the volume of responses they could not provide any timeframe to respond (we pointed out that almost 83% of the comments were about the same issue: labeling Gluten). Additionally, the FDA officials including Dr. Susan Mayne suggested that they did not have the existing statutory authority under FALCPA to name Gluten as a Major Food Allergen or require that Gluten be labeled on all food packages. To that end, the FDA advised us that we should go to Congress to get new legislation passed if we wanted to require that Gluten be labeled on all packaged foods.⁷⁵

This is especially troublesome since according to the 2019 Congressional testimony of Marilyn Geller, CEO of the Celiac Disease Foundation, “Americans are dying because we haven't paid sufficient attention to this disease.”⁷⁶ We just do not have the privilege of time to wait any longer. See Section II in this Citizen Petition entitled “Statement of Legal Grounds.” Also, see Section IX in this Citizen Petition entitled, “FDA's Draft Guidance Illustrates Bias Against Celiac Disease.”

⁷¹ The FDA's final rule defining Gluten Free for food labeling became effective on September 4, 2013, and August 5, 2014 was the date when FDA-regulated foods labeled Gluten Free must comply with all requirements established by the final rule.

<https://www.federalregister.gov/documents/2013/08/05/2013-18813/food-labeling-gluten-free-labeling-of-foods> , and

<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/small-entity-compliance-guide-gluten-free-labeling-foods#>

⁷² <https://www.fda.gov/consumers/consumer-updates/gluten-free-means-what-it-says>

⁷³ <https://www.regulations.gov/docket/FDA-2021-N-0553/comments>

⁷⁴ <https://www.regulations.gov/docket/FDA-2021-N-0553/comments?filter=celiac>

⁷⁵ www.celiacjourney.com/fda2

⁷⁶ <https://www.youtube.com/live/KGRHg-840KE?feature=share&t=11485> , and

<https://www.congress.gov/event/117th-congress/senate-event/LC65823/text?s=1&r=42>

These issues are also further discussed in greater detail in this Citizen Petition in Section V. entitled, “President Biden’s Executive Order 13985 On Advancing Racial Equity and Support for Underserved Communities Through the Federal Government & President Biden’s Executive Order 14091: Further Advancing Racial Equity and Support for Underserved Communities Through the Federal Government.”

Unfortunately, the FDA’s Draft Guidance, which was published in April 2022 is incongruent with HHS Equity Action Plan as also detailed herein.

I. The Findings of the Reagan-Udall Foundation’s Expert Panel Shine a Bright Light on Our Lived Experience and Frustrations in Requesting More Consumer Protection from the FDA

According to the Reagan-Udall Foundation’s 2022 “Operational Evaluation of the FDA’s Human Foods Program: A Report of the Human Foods Independent Expert Panel” (“Reagan-Udall Report”), the experts found that there is a key issue pertaining to the FDA’s culture:

“FDA has dedicated staff who are committed to protecting public health, but the current culture of the FDA Human Foods Program is inhibiting its ability to effectively accomplish this goal. The dedication to public service and loyalty to the Agency’s mission contribute positively to the culture of the Human Foods Program. Most FDA employees understand the immense responsibility of the Agency’s Human Foods Program, appreciate the importance of their work, and share a common value of striving to protect public health. **However, the current culture, structure, and governance model detract from the Program’s effectiveness.**

There are several factors contributing to this culture, including the lack of a clear vision and mission; a disparate structure and a consensus governance model; competing priorities; and the lack of a strong, supportive leader and, when the situation requires, an ultimate decision-maker, who is responsible for the Human Foods Program. **The lack of a clear overarching leader of the Human Foods Program has contributed to a culture of indecisiveness and inaction and created disincentives for collaboration.**”⁷⁷ (emphasis added)

In terms of decision-making, the Reagan-Udall Report also found that,

“The Human Foods Program approach of relying on consensus has significant drawbacks for making decisions about taking regulatory action. FDA’s culture should foster collaboration and give high priority to finding the best solution over yielding unanimous agreement. While striving for consensus can be beneficial in innovating and gaining better insight on issues, ultimately leading to greater buy in, it can also lead to agreement around the lowest common denominator if consensus is not driven

⁷⁷ “Operational Evaluation of the FDA’s Human Foods Program: A Report of the Human Foods Independent Expert Panel.” Henney, et. al; 2022, Reagan-Udall Foundation for the Food and Drug Administration, December 2022, <https://reaganudall.org/sites/default/files/2022-12/Human%20Foods%20Program%20Independent%20Expert%20Panel%20Final%20Report%20120622.pdf>

by an underlying spirit of resolute decision-making, collaboration, and trust. Lack of clarity in the decision-making structure further compromises reaching consensus. Decision-making under the Human Foods Program Governance Board⁷⁸ appears to generate cross-Center inertia, where the Board may be used more often to stop an initiative than to advance it. For more operational, and program-specific decisions, collections of individuals from various offices contribute, but may not be unified in their priorities nor have a clear articulation of the final decision, or the process used to generate a final decision. **In the absence of a collaborative, problem-solving posture enabled by a clear process supporting timely decisions, the scales can be tipped in favor of inaction, minimizing risk, and maintaining the status quo. This culture creates an environment where decision-making is unacceptably slow. From an external perspective, the Human Foods Program can be left appearing sluggish and non-responsive to public health concerns.**⁷⁹ (emphasis added)

“There is no clear Human Foods Program leader or decision-maker, outside of the Commissioner. Although the missions of CFSAN and OFPR [Office of Food Policy and Response] have differences on paper, staff are often left wondering which program is responsible for decision-making.”⁸⁰

To those ends, we are eagerly anticipating the opportunity to meet with the FDA’s James “Jim” Jones who starts his duties with the FDA as Deputy Commissioner for Human Foods on September 24, 2023.⁸¹

J. The Labeling of Gluten as a Major Food Allergen Sits at the Intersection of President Biden’s Executive Orders on Advancing Equity for Underserved Communities, the White House Conference and National Strategy on Hunger, Health, & Nutrition, and Human Rights

The labeling of Gluten as a Major Food Allergen sits at the intersection of President Biden’s Executive Orders 13985 and 14091⁸² on advancing equity for underserved communities for

⁷⁸ FDA Human Foods Program Governance Board Charter, Oct 2019

⁷⁹ “Operational Evaluation of the FDA’s Human Foods Program: A Report of the Human Foods Independent Expert Panel.” Henney, et. al; 2022, Reagan-Udall Foundation for the Food and Drug Administration, December 2022, <https://reaganudall.org/sites/default/files/2022-12/Human%20Foods%20Program%20Independent%20Expert%20Panel%20Final%20Report%20120622.pdf>

⁸⁰ “Operational Evaluation of the FDA’s Human Foods Program: A Report of the Human Foods Independent Expert Panel.” Henney, et. al; 2022, Reagan-Udall Foundation for the Food and Drug Administration, December 2022, <https://reaganudall.org/sites/default/files/2022-12/Human%20Foods%20Program%20Independent%20Expert%20Panel%20Final%20Report%20120622.pdf>

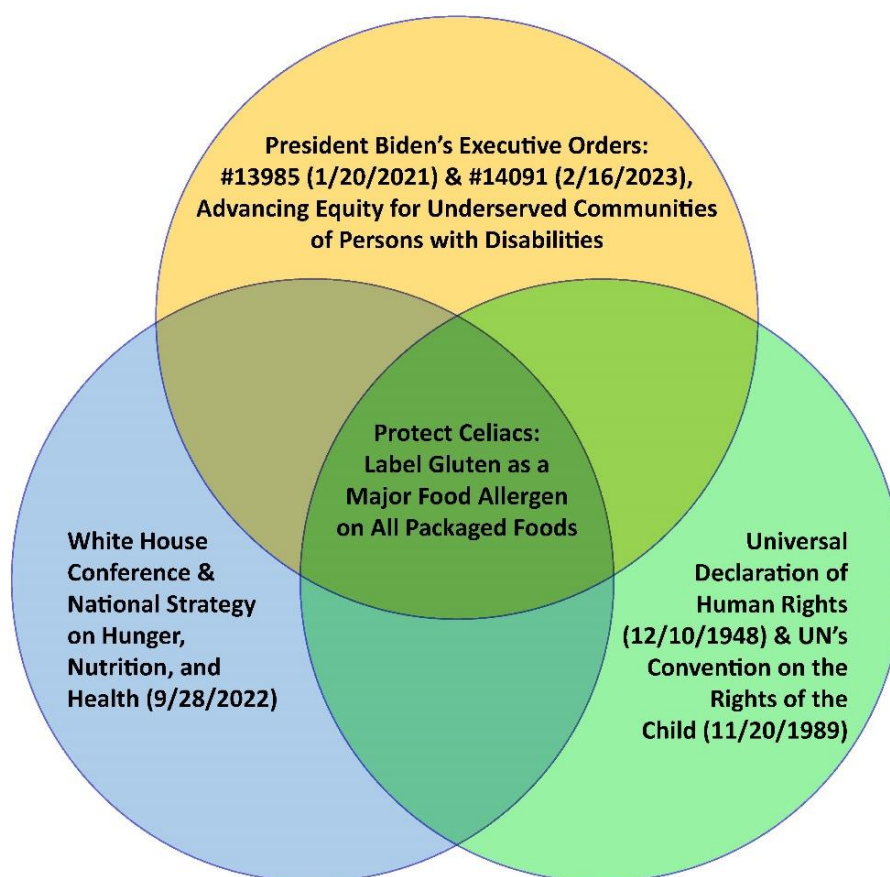
⁸¹ Mr. Jones is scheduled to start work at the FDA on September 24, 2023.

<https://www.fda.gov/news-events/press-announcements/fda-names-first-deputy-commissioner-proposed-unified-human-foods-program>

⁸² <https://www.federalregister.gov/documents/2023/02/22/2023-03779/further-advancing-racial-equity-and-support-for-underserved-communities-through-the-federal>

persons with disabilities such as 3.3 million American Celiacs (see the following sections in this Citizen Petition: Section V. “President Biden’s Executive Order 13985 On Advancing Racial Equity and Support for Underserved Communities Through the Federal Government & President Bidens Executive Order 14091: Further Advancing Racial Equity and Support for Underserved Communities Through the Federal Government”; Section V.G., “Universal Declaration of Human Rights -- The Right to Feed Oneself in Dignity”; and Section V.H., “UN’s Convention on the Rights of the Child”).

Figure 1 - The Labeling of Gluten as a Major Food Allergen Sits at the Intersection of President Biden’s Executive Orders on Advancing Equity for Underserved Communities, the White House Conference and National Strategy on Hunger, Health, & Nutrition and Human Rights



The follow up to the September 2022 White House Conference represents a once in a generational opportunity to catalyze the public and private sectors around a whole-of-government coordinated strategy to accelerate progress and drive transformative change in the U.S. to eliminate hunger, improve nutrition, and reduce diet-related disease.⁸³ To that end, we are asking the President, the HHS Secretary and the FDA Commissioner to address the historically underserved and unmet needs of 3.3 million Americans with Celiac Disease with the naming of Gluten as a Major Food Allergen and the labeling of Gluten on all packaged foods in the U.S., just like it is done in 85 countries around the world

⁸³ www.celiacjourney.com/takeaways

As President Joe Biden said at the White House Conference on Hunger, Health, and Nutrition,

“[I]f a parent cannot feed a child, there’s nothing else that matters for that parent. **If you look at your child and you can’t feed your child, what the hell else matters?** I really mean it.”⁸⁴ (emphasis added)

Unfortunately, President Biden’s remarks ring true for us – “If you look at your child and you can’t feed your child, what the hell else matters?” We have lived this food insecurity experience that President Biden spoke of in the absence of required labeling of Gluten as a Major Food Allergen, especially eating out of the house, and our son Jax getting violently ill after being Glutened (accidentally ingesting Gluten).

For 3.3 million American Celiacs, integrating nutrition and health and empowering all Celiac consumers to make and have access to healthy choices is a function of labeling Gluten as a Major Food Allergen.

These issues are also further discussed in greater detail in this Citizen Petition in Section V. entitled, “President Biden’s Executive Order 13985 On Advancing Racial Equity and Support for Underserved Communities Through the Federal Government & President Biden’s Executive Order 14091: Further Advancing Racial Equity and Support for Underserved Communities Through the Federal Government.”

Let’s label Gluten now as a Major Food Allergen and protect 3.3 million American Celiacs so that they can live their best lives. As President Biden said at the White House Conference,

“This is the United States of America. (Applause.) There is nothing -- nothing, nothing -- I really mean it -- there’s nothing beyond our capacity when we work together, so let’s work together.”⁸⁵

K. Preliminary Statement on Human Rights & Celiac Disease

It is instructive to view this Citizen Petition (and all comments received on the FDA’s Draft Guidance⁸⁶) through the lens that the only available treatment for Celiac -- Gluten Free food -- must also be viewed as a human rights issue.

According to the United Nations, “Human rights are rights inherent to all human beings, regardless of race, sex, nationality, ethnicity, language, religion, or any other status. Human rights include the right to life and liberty, freedom from slavery and torture, freedom of opinion and expression, the right to work and education, and many more. Everyone is entitled to these rights, without discrimination.”⁸⁷

For a frame of reference, it is helpful to distinguish human rights from civil rights, even though there is overlap between the two types of rights. Human rights are existential, or in other words

⁸⁴ <https://www.whitehouse.gov/briefing-room/speeches-remarks/2022/09/28/remarks-by-president-biden-at-the-white-house-conference-on-hunger-nutrition-and-health/#>

⁸⁵ <https://www.whitehouse.gov/briefing-room/speeches-remarks/2022/09/28/remarks-by-president-biden-at-the-white-house-conference-on-hunger-nutrition-and-health/>

⁸⁶ <https://www.regulations.gov/docket/FDA-2021-N-0553/comments?filter=gluten>

⁸⁷ “Human Rights.” United Nations. <https://www.un.org/en/global-issues/human-rights>

arise simply by the state of being a human being. Civil rights, on the other hand, are those rights that a person is entitled to by virtue of citizenship in a particular nation or state. For example, in the United States, Civil rights are enshrined for American citizens by the Constitution of the United States.

The Universal Declaration of Human Rights expressly and directly links “health and well-being” with adequate food.⁸⁸ According to the United Nations Office of the Commissioner for Human Rights (“UN Human Rights Commissioner”), “The right to [adequate] food is recognized in the 1948 Universal Declaration of Human Rights as part of the right to an adequate standard of living and is enshrined in the 1966 International Covenant on Economic, Social and Cultural Rights.”⁸⁹ According to the UN Human Rights Commissioner, “Human rights are interdependent, indivisible and interrelated. This means that violating the right to [adequate] food may impair the enjoyment of other human rights, such as the right to health, education or life, and vice versa.”⁹⁰

The United Nations Convention on the Rights of the Child expressly and directly links the importance of “combating [pediatric] disease and malnutrition, including within the framework of primary health care... through the provision of adequate nutritious foods.” The Convention on the Rights of the Child also addresses “the right of the child to the enjoyment of the highest attainable standard of health and to facilities for the treatment of illness and rehabilitation of health. States Parties shall strive to ensure that no child is deprived of his or her right of access to such health care services.”⁹¹

According to the United Nations Office of the Commissioner for Human Rights, the Right to Adequate Food means that “**the food must satisfy dietary needs, taking into account the individual’s... health... Food should be safe for human consumption and free from adverse substances...**”⁹² (emphasis added)

With respect to the FDA’s Draft Guidance and food labeling in the U.S., the Right to Adequate Food encompasses that the Celiac community has the right to adequate, complete and truthful ingredients information in terms of mandatory labeling of Gluten in the food and medicine that they consume.

See Section XII in the Citizen Petition entitled, “The Only Available Treatment for Celiac Gluten Free Food Must Be Viewed as a Human Right.”

L. HHS Secretary Xavier Becerra Has Existing Statutory Authority to Label Gluten Now

According to the Food & Drug Law Journal’s seminal article in 2006 that was edited by Peter Barton Hutt, the former Chief Counsel to the FDA, and entitled, “When Food Is Poison: The History, Consequences, and Limitations of the Food Allergen Labeling and Consumer Protection

⁸⁸ Universal Declaration of Human Rights, Article 25, <https://www.un.org/en/about-us/universal-declaration-of-human-rights>

⁸⁹ <https://www.ohchr.org/sites/default/files/Documents/Publications/FactSheet34en.pdf>

⁹⁰ <https://www.ohchr.org/sites/default/files/Documents/Publications/FactSheet34en.pdf>

⁹¹ “Convention on the Rights of the Child.” United Nations. 20 November 1989.

<https://www.ohchr.org/Documents/ProfessionalInterest/crc.pdf>

⁹² <https://www.ohchr.org/Documents/Publications/FactSheet34en.pdf>

Act of 2004” (“When Food Is Poison”),⁹³ the Secretary of HHS has existing statutory authority as codified by the Food Allergen Labeling and Consumer Protection Act of 2004 (“FALCPA”) to label Gluten as a Major Food Allergen. See Citizen Petition Exhibit 5.

The FALCPA “does not preclude FDA from expanding via regulation the list of major allergens requiring identification under the FALCPA’s labeling scheme.”⁹⁴ Section 203(b) states that the labeling requirements established under new section 403(w) “**do not prevent the Secretary from requiring labels or labeling changes for other food allergens that are not major food allergens.**”⁹⁵ (emphasis added)

This is discussed in greater detail in this Citizen Petition in the section entitled, “Statement of Legal Grounds.”

M. Our Guiding Path

In Judaism, the process of “teshuva” implies both reflection on the past and the initiation of different action in the future. The linguistic root of teshuva is the same as the word “to return” or “to go back.” Etymologically, teshuva implies a process of returning to the past in order to acknowledge it, apologize, and make amends. In order to better protect more than 3.3 million American Celiacs, including our son Jax, we view our Citizen Petition to require the declaration of Gluten on all packaged foods in the U.S. through the lens of teshuva.

⁹³ Derr, Laura E. “When Food Is Poison: The History, Consequences, and Limitations of the Food Allergen Labeling and Consumer Protection Act of 2004.” *Food and Drug Law Journal*, vol. 61, no. 1, 2006, pp. 65–165. JSTOR, <https://www.jstor.org/stable/i26659390>

⁹⁴ When Food is Poison, Page 141, including footnotes 423-424: “See FALCPA 203(b), 21 U.S.C.A. 343(note); FALCPA 203(a), 21 U.S.C.A. 343(x). The Senate Committee Report states that it intends for any regulations issued by FDA requiring the identification of additional allergens to prescribe disclosure in ‘a manner consistent with’ the FALCPA. S. Rep. No. 108-226, at 10.” (Source: <https://www.congress.gov/108/crpt/srpt226/CRPT-108srpt226.pdf>) “The legislation also adds a second misbranding provision to account for other food allergens. In particular, section 403(x) provides that FDA has the authority to require by regulation appropriate labeling of any spice, flavoring, coloring, or incidental additive ingredient that is, or includes as a constituent, a food allergen that is not a major food allergen. The committee does not intend the listing of all spices or flavorings in a product but intends that the Secretary will require the food allergen to be identified on the label in a manner consistent with this legislation.” <https://www.congress.gov/108/crpt/srpt226/CRPT-108srpt226.pdf>

⁹⁵ H.R. Rep. No. 108-608, at 18. (2004), <https://www.congress.gov/108/crpt/hrpt608/CRPT-108hrpt608.pdf>

II. Statement of Legal Grounds

“What is food to one man may be fierce poison to others.”
Lucretius (c. 99 b.c.e.-c. 55 b.c.e.), Roman poet and philosopher

“EQUAL JUSTICE UNDER LAW”⁹⁶

A. FDA Has Statutory Authority to Require the Labeling of Products Containing Gluten

According to the Reagan-Udall Report, “Food safety and nutrition activities are both critically important to the health and wellbeing of our nation -- albeit in different ways -- and each should be recognized and given high priority within FDA... The FDA has a key role within a broader, whole-of-government approach to help reduce the burden of chronic diseases and advance health equity by helping to improve dietary patterns in the U.S.⁹⁷ -- the ‘applied nutrition’ functions of CFSAN.” “According to the Office of the Commissioner, the current FDA Foods Regulatory Program has nine primary functions.” Of the nine primary functions, the first one is “Standards setting and policy development for food safety, nutrition, labels, regulatory program frameworks, food defense and other requirements, including development of regulatory methods.”⁹⁸ (emphasis added)

The FDA has clear authority under the law to issue regulations to require the label declaration of additional allergens, and that authority was strengthened and clarified thanks to the FALCPA. Under 21 U.S.C. § 343(x), which provides: “a spice, flavoring, coloring, or incidental additive that is, or that bears or contains, a food allergen (other than a major food allergen), as determined by the Secretary by regulation, shall be disclosed in a manner specified by the Secretary by regulation.” Accordingly, we request that the Secretary publish a rule to regulate Gluten in a manner similar to a Major Food Allergen, and that labels be required to state when a product “may contain” Gluten due to cross-contamination.

Additionally, the FDA may require labeling pursuant to its authority to enforce the prohibition on misbranded foods in Section 403(a) of the FDCA. Under the FDCA’s misbranding provisions, a food is “misbranded” if its label is “false or misleading in any particular.”⁹⁹ To determine whether a product is misbranded, the FDA must evaluate whether, *inter alia*, the label “fails to reveal facts material in the light of representations [made] or material with respect to consequences which may result from the use of the article to which the labeling or advertising relates under such conditions of use as are customary or usual.”¹⁰⁰ Acting under its general

⁹⁶ <https://www.supremecourt.gov/about/constitutional.aspx>

⁹⁷ FDA’s Nutrition Initiative’s. US Food and Drug Administration. Updated August 16, 2023. Accessed August 30, 2023.

<https://www.fda.gov/food/food-labeling-nutrition/fdas-nutrition-initiatives>

⁹⁸ “Operational Evaluation of the FDA’s Human Foods Program: A Report of the Human Foods Independent Expert Panel.” Henney, et. al; 2022, Reagan-Udall Foundation for the Food and Drug Administration, December 2022,

[https://reaganudall.org/sites/default/files/2022-](https://reaganudall.org/sites/default/files/2022-12/Human%20Foods%20Program%20Independent%20Expert%20Panel%20Final%20Report%20120622.pdf)

[12/Human%20Foods%20Program%20Independent%20Expert%20Panel%20Final%20Report%20120622.pdf](https://reaganudall.org/sites/default/files/2022-12/Human%20Foods%20Program%20Independent%20Expert%20Panel%20Final%20Report%20120622.pdf)

⁹⁹ FDCA § 403(a) (codified at 21 U.S.C. § 343(a)).

¹⁰⁰ FDCA § 201(n) (codified at 21 U.S.C. § 321(n)).

authority, the FDA can “promulgate regulations for the efficient enforcement of [the FDCA].”¹⁰¹

Congress has determined that the failure to use ordinary names for major allergens (including those in flavorings, colorings, and incidental additives¹⁰²) is misleading to consumers when the foods are regulated by FDA. In Section 202(5) of the FALCPA, Congress found that some of the current terms used for an ingredient may be unfamiliar to consumers, and many consumers “may not realize the ingredient is derived from, or contains, a major food allergen; and in other cases the ingredient may be declared as a class, including spices, flavorings, and certain colorings, or are exempt from the ingredient labeling requirements, such as incidental additives.”¹⁰³ Specifically, further clarification of the source of a specific ingredient in a parenthetical statement in the ingredients statement on labeling, e.g., “whey (from milk),” is encouraged because the more recognizable term better informs consumers.¹⁰⁴ In the case of the FDA better protecting the Celiac community, that would include a clear statement in the ingredients statement on labeling, e.g., “flour (from Rye),” “flour (from Barley),” “flour (from Oats),”

The statute is clear: the failure of a food label to provide material information regarding the potential adverse consequences of eating a food can cause a food to be falsely or misleadingly labeled, and therefore misbranded.

B. The FDCA Confers Broad Authority on the FDA to Effectuate the Important Public Policy Goals of the Statute, Including the Policies Behind the FALCPA.

The FDA has broad authority to promulgate regulations for the efficient enforcement of the FDCA.¹⁰⁵ This authority is well-established and is supported by the public policy of protecting consumers by promoting honest and fair dealing where consumers have the right to know if there are potentially life-threatening food allergens in various food items.¹⁰⁶

The general purpose of the FDCA is to “protect unwary customers in vital matters of health...”¹⁰⁷ Given the Act’s broad remedial purpose, courts have construed the statute liberally.¹⁰⁸ The

¹⁰¹ FDCA § 701(a) (codified at 21 U.S.C. § 371(a)).

¹⁰² For meat and poultry products, the Secretary of Agriculture has the legal authority to determine whether spices, flavorings, and colorings shall be listed separately or designated without naming each one. Section 1(n)(9) of the Federal Meat Inspection Act (“FMIA”) and section 4(h)(9) of the Poultry Products Inspection Act (“PPIA”), 21 U.S.C. 601(n)(9) and 453(h)(9). The Secretary can use this legal authority to require that flavorings or colorings containing a Major Food Allergen be separately identified.

¹⁰³ See 21 U.S.C.S. § 343; FALCPA; Findings. Act Aug. 2, 2004, P.L. 108-282, Title II, § 202.

¹⁰⁴ Center for Science in the Public Interest,

<https://www.cspinet.org/sites/default/files/media/documents/resource/11-18-sesame-petition.pdf>

¹⁰⁵ 21 U.S.C.S. § 371(a).

¹⁰⁶ See, e.g., *A. E. Staley Mfg. Co. v. Secretary of Agriculture*, 120 F.2d 258, 260 (7th Cir. 1941).

¹⁰⁷ *United States v. 216 Cartoned Bottles, More or Less, of... Sudden Change*, 409 F.2d 734, 741 (2d Cir. 1969).

¹⁰⁸ *United States v. An Article of Drug... Bacto-Unidisk*, 394 U.S. 784, 798 (1969) (applying the well-accepted principle that remedial legislation such as the [FDCA] is to be given a liberal construction consistent with the Acts overriding purpose to protect the public health . . .); *216 Cartoned Bottles*, 409 F.2d at 741 ([T]he Act... must be given a liberal construction to effectuate [its] high purpose.).

FDCA confers authority on FDA to enforce the provisions of the statute by regulation (21 U.S.C. § 371(a)), and this regulatory authority, too, is “broad.”¹⁰⁹ Finally, in evaluating the exercise of FDA’s regulatory authority, courts accord great deference to the Agency’s decisions, especially where they implicate the evaluation of scientific data within the Agency’s technical expertise.¹¹⁰

The “FALCPA was designed to improve food labeling information so that consumers who suffer from food allergies - especially children and their caregivers - will be able to recognize the presence of an ingredient that they must avoid.”¹¹¹ Given the severity and the apparent growing prevalence of the Gluten allergy with Celiac Disease, it would be consistent with existing FDA policy regarding allergen labeling to label the presence of Gluten by issuing specific Gluten-labeling regulations for both foods and cosmetics, as the FDA did in 2009 for carmine and cochineal.¹¹²

C. Findings of FDA’s Former Chief Counsel, Harvard Law Professor and Partner, Covington & Burling and Former Harvard Law School Student’s on HHS Secretary’s Existing Statutory Authority in the Food & Drug Law Journal

According to the Food & Drug Law Journal’s seminal article in 2006 that was entitled, “When Food Is Poison: The History, Consequences, and Limitations of the Food Allergen Labeling and Consumer Protection Act of 2004” (“When Food Is Poison”),¹¹³ **FALCPA “does not preclude FDA from expanding via regulation the list of major allergens requiring identification under the FALCPA’s labeling scheme.”**¹¹⁴ Section 203(b) states that the labeling requirements

¹⁰⁹ *Cosmetic, Toiletry and Fragrance Assn v. Schmidt*, 409 F.Supp. 57, 64 (D.D.C. 1976) (upholding FDA Commissioners authority to require warning statements on aerosolized food, drug, and cosmetic products).

¹¹⁰ *International Fabricare Inst. v. U.S. EPA*, 972 F.2d 384, 389 (D.C. Cir. 1992). See also *Community Nutrition Institute v. Young*, 476 U.S. 974, 981-82 (1986) (noting that the FDA has been delegated broad discretion by Congress in any number of areas and deferring to Agency expertise).

¹¹¹ U.S. Food & Drug Administration. Food Allergen Labeling and Consumer Protection Act of 2004 Questions and Answers. Updated July 18, 2006. <http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/allergens/ucm106890.htm#q4>.

¹¹² Listing of Color Additives Exempt from Certification; Food, Drug and Cosmetic Labeling, Cochineal Extract and Carmine Declaration, 74 FR 207, Jan. 5, 2009.

¹¹³ Derr, Laura E. “When Food Is Poison: The History, Consequences, and Limitations of the Food Allergen Labeling and Consumer Protection Act of 2004.” *Food and Drug Law Journal*, vol. 61, no. 1, 2006, pp. 65–165. JSTOR, <https://www.jstor.org/stable/i26659390>

¹¹⁴ When Food is Poison, Page 141, including footnotes 423-424: “See FALCPA 203(b), 21 U.S.C.A. 343(note); FALCPA 203(a), 21 U.S.C.A. 343(x). The Senate Committee Report states that it intends for any regulations issued by FDA requiring the identification of additional allergens to prescribe disclosure in ‘a manner consistent with’ the FALCPA. S. Rep. No. 108-226, at 10.” (Source: <https://www.congress.gov/108/crpt/srpt226/CRPT-108srpt226.pdf>) “The legislation also adds a second misbranding provision to account for other food allergens. In particular, section 403(x) provides that FDA has the authority to require by regulation appropriate labeling of any spice, flavoring, coloring, or incidental additive ingredient that is, or includes as a constituent, a food allergen that is not a major food allergen. The committee does not intend the listing of all spices or flavorings in a product but intends that the Secretary will

established under new section 403(w) “**do not prevent the Secretary from requiring labels or labeling changes for other food allergens that are not major food allergens.**”¹¹⁵ (emphasis added)

When Food is Poison was written by Laura Derr when she was a student at Harvard Law School, under the supervision of Lecturer on Law Peter Barton Hutt, Partner at Covington & Burling in Washington, D.C., for Harvard Law School’s Winter 2005 Food and Drug Law course. Mr. Hutt was also former Chief Counsel to the FDA from 1971-1975. When Food is Poison won First Place in the 2005 H. Thomas Austern Memorial Writing Competition (long papers) sponsored by the Food and Drug Law Institute.¹¹⁶

D. Labeling Gluten on All Packaged Foods in the U.S. Would Be in a Manner Consistent With the FALCPA

The labeling of Gluten on all packaged foods in the U.S. would be in a manner consistent with the letter and spirit of FALCPA. For example, FALCPA’s Section 2, Findings (“FALCPA’s Findings”) expressly discuss Celiac Disease as one of its six key findings.¹¹⁷ There are no other food allergens or diseases other than the Top 8 Major Food Allergens, Gluten and Celiac expressly mentioned in FALCPA’s Findings. Adding Gluten to the list of Major Food Allergens would be in a manner consistent with the consumer protection law in how the other top 8 Major Food Allergens have been required to be labeled since January 1, 2006. For more information on FALCPA’s Findings, see Section VII. in this Citizen Petition entitled, “FALCPA Fell Short in Safeguarding Celiacs,” and note Section VII.D. specifically.

E. Rules for Current Good Manufacturing Practices and the Food Safety Modernization Act

The FDA has also incorporated the Major Food Allergens defined in the FALCPA into its rules for current good manufacturing practices (“CGMP”) and into food safety regulations promulgated under the Food Safety Modernization Act (“FSMA”). These food safety rules identify Major Food Allergens as a form of “chemical hazard,”¹¹⁸ and require companies to control the hazard by providing assurance that it will be “significantly minimized or prevented.”¹¹⁹ This includes, in the case of allergens, “ensuring protection of food from allergen cross-contact,”¹²⁰ which is defined as the unintentional incorporation of a food allergen into a food.¹²¹ Food safety rules also require accurate labeling of the finished food, including ensuring that the food is not misbranded by the existence of undeclared allergens.¹²²

require the food allergen to be identified on the label in a manner consistent with this legislation.” <https://www.congress.gov/108/crpt/srpt226/CRPT-108srpt226.pdf>

¹¹⁵ H.R. Rep. No. 108-608, at 18. (2004), <https://www.congress.gov/108/crpt/hrpt608/CRPT-108hrpt608.pdf>

¹¹⁶ <https://www.fdli.org/career/austern-writing-competition/>

¹¹⁷ <https://www.fda.gov/food/food-allergensgluten-free-guidance-documents-regulatory-information/food-allergen-labeling-and-consumer-protection-act-2004-questions-and-answers>

¹¹⁸ 21 C.F.R. 117.130(b)(ii); 21 C.F.R. 117.3 (defining food allergen to mean Major Food Allergens).

¹¹⁹ 21 CFR 117.135(a)(1).

¹²⁰ 21 CFR 117.135(c)(2)(i).

¹²¹ 21 CFR 117.3.

¹²² 21 CFR 117.135(c)(2)(ii).

III. Celiac Disease - Statement of Factual Grounds

“All disease begins in the gut.”

-- Hippocrates

“Let food be thy medicine and medicine be thy food.”

-- Hippocrates

“Strict adherence to a gluten-free diet is the *only* available treatment. But, as our celiac disease researchers agree, ‘There is no such thing as a truly gluten-FREE diet’ because of the constant risk of cross-contact with gluten, and gluten is in 80% of our foodstuffs.”¹²³

-- Dr. Stefano Guandalini and Dr. Bana Jabri of the University of Chicago Celiac Disease Center

A. Overview

Celiac Disease is an immune-mediated food allergy,¹²⁴ auto-immune disease¹²⁵ and digestive disease¹²⁶ that is triggered by eating Gluten. Accordingly, Celiac Disease does not fit into a nice little box or category. We agree with the FDA that people with Celiac Disease “face potentially life-threatening illnesses if they eat gluten, typically found in breads, cakes, cereals, pastas, and many other foods... There is no cure for celiac disease and the only way to manage the disease is to avoid eating gluten.”¹²⁷

According to the NIH’s “Notice of Special Interest (NOSI): Accelerating Progress in Celiac Disease Research” that was published on November 23, 2021, there are more than 3.3 million Americans who have Celiac Disease.

“Celiac disease is an autoimmune disease that occurs in genetically susceptible individuals who develop an immune response to ingested gluten. This disease affects greater than 1% of the US population [greater than 3.3 million Americans¹²⁸], and

¹²³ <https://www.congress.gov/event/117th-congress/senate-event/LC65823/text?s=1&r=42> ; “Patient Perception of Treatment Burden is High in Celiac Disease Compared to Other Common Conditions,” PMC, National Library of Medicine, National Institutes of Health, July 1, 2014, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4159418/> ; Roy, A., Minaya, M., Monegro, M. et al. Partner Burden: A Common Entity in Celiac Disease. *Dig Dis Sci* 61, 34513459 (2016), <https://doi.org/10.1007/s10620-016-4175-5>; and “What is Celiac Disease?”, Celiac Disease Foundation, <https://celiac.org/about-celiac-disease/what-is-celiac-disease/>

¹²⁴ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4241964/pdf/nihms247178.pdf> (pages 5, 11-12); and <https://www.fda.gov/media/157637/download> (page 10)

¹²⁵ <https://grants.nih.gov/grants/guide/notice-files/not-ai-22-004.html#>

¹²⁶ <https://www.niddk.nih.gov/health-information/digestive-diseases>

¹²⁷ <https://www.fda.gov/consumers/consumer-updates/gluten-free-means-what-it-says>

¹²⁸ The U.S. Census estimated a population of 261 million adults and 72 million children under age 18 in 2022. Estimates of the Total Resident Population and Resident Population Age 18 Years and Older for the United States, Regions, States, District of Columbia, and Puerto Rico: July 1, 2022 (SCPRC-EST2022-18+POP), U.S. Census Bureau, Population Division, December 2022. <https://www2.census.gov/programs-surveys/popest/tables/2020-2022/state/detail/SCPRC-EST2022-18+POP.xlsx>

incidence appears to have been increasing over the last several decades. The only known treatment is life-long strict avoidance of all forms of wheat, rye, and barley. **Although a gluten-free diet is an effective treatment in many individuals, recent research has revealed that up to 50% of individuals following a gluten-free diet are inadvertently exposed to gluten, and a substantial minority develop persistent or recurrent symptoms.**¹²⁹ (emphasis added)

According to the Celiac Disease Foundation, researchers are finding that the prevalence of Celiac Disease is doubling approximately every 15 years, making it a public health epidemic.¹³⁰ Celiacs are glutened regularly and have their major life activities such as eating, sleeping, thinking and/or learning impacted on an ongoing basis. Beyond Celiac reported that 44% of people with Celiac Disease who follow a strict Gluten Free diet still get glutened once a month.¹³¹

According to Dr. Stefano Guandalini and Dr. Bana Jabri of the University of Chicago Celiac Disease Center, “Strict adherence to a gluten-free diet is the *only* available treatment. But, as our celiac disease researchers agree, ‘There is no such thing as a truly gluten-FREE diet’ because of the constant risk of cross-contact with gluten, and gluten is in 80% of our foodstuffs.”¹³²

Importantly, unlike food allergies with IgE-Mediated mechanisms, there is no rescue medicine (i.e., adrenaline or antihistamine) to treat the accidental ingestion of Gluten and the start of the auto-immune cascade in food allergy with Non-IgE-Mediated mechanisms such as Celiac Disease. Additionally, those with a Non-IgE-Mediated food allergy to Gluten cannot outgrow their food allergy – Celiac is lifelong (until such time as a cure may be developed).

Insulin is to Diabetics as Gluten Free Food is to Celiacs

Food is medicine for Celiacs. As Jax Bari explained to President Biden when they met, “insulin is to Diabetics as Gluten Free food is to Celiacs.”¹³³ According to Dr. Alessio Fasano, Director of the Center for Celiac Research and Treatment at Massachusetts General Hospital “[f]or people with celiac disease, the gluten-free diet is like insulin for diabetics.”¹³⁴ In the context of the analogy that Diabetes is to Celiac as insulin is to Gluten Free foods, it is instructive to view President Biden’s remarks at the 2022 State of the Union (“SOTU”) on the struggles that many families have to make on insulin and how that impacts your family and dignity:

“I spoke with Joshua’s [Davis] mom [Shannon Davis]. Imagine what it’s like to look at your child who needs insulin to stay healthy and have no idea how in God’s name you’re going to be able to pay for it -- what it does to your family, but what it does to your

¹²⁹ <https://grants.nih.gov/grants/guide/notice-files/NOT-AI-22-004.html>

¹³⁰ <https://celiac.org/april-2019-congressional-testimony-by-ceo-marilyn-g-geller/>

¹³¹ <https://twitter.com/abast/status/1551780196243603457>

¹³² <https://www.congress.gov/event/117th-congress/senate-event/LC65823/text?s=1&r=42> ; “Patient Perception of Treatment Burden is High in Celiac Disease Compared to Other Common Conditions,” PMC, National Library of Medicine, National Institutes of Health, July 1, 2014, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4159418/> ; Roy, A., Minaya, M., Monegro, M. et al. Partner Burden: A Common Entity in Celiac Disease. *Dig Dis Sci* 61, 34513459 (2016), <https://doi.org/10.1007/s10620-016-4175-5>; and “What is Celiac Disease?”, Celiac Disease Foundation, <https://celiac.org/about-celiac-disease/what-is-celiac-disease/>

¹³³ www.celiacjourney.com/potus

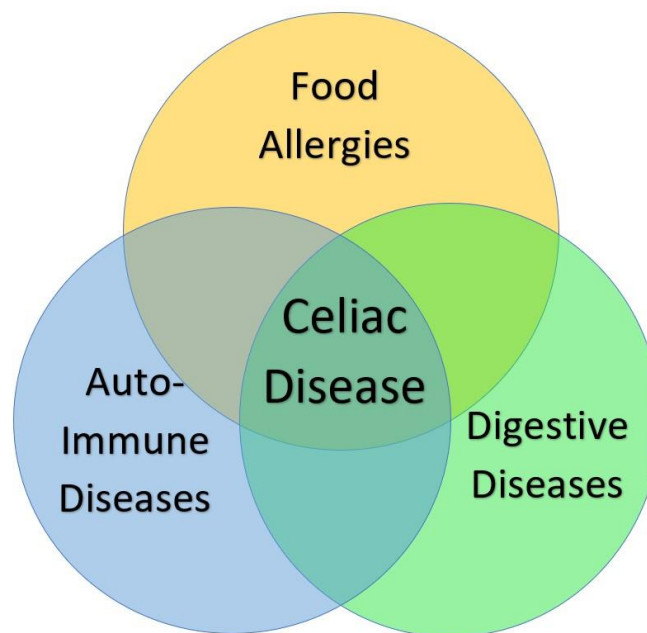
¹³⁴ <https://amp.cnn.com/cnn/2017/03/01/health/gluten-free-diet-history-explainer/index.html>

dignity, your ability to look your child in the eye, to be the parent you expect yourself to be. I really mean it. Think about that.”¹³⁵

Just like President Biden’s SOTU addressed the impact of insulin pricing and Diabetes management for kids, we have had such similar experiences with managing our son’s Celiac Disease. We have seen firsthand what Celiac has done to our family and what Celiac has done to our dignity. We have seen how Celiac impacts our ability to look Jax in the eye while explaining his food allergy to others who do not understand, trying to find safe food for him (especially when eating away from home), dealing with society’s biases against his disease and treatment therefor, consoling him when he cannot find safe food and must watch others around him eating when he cannot, comforting him when he has become violently ill from eating Gluten, and empathizing with his frustrations regarding the Federal government’s failures to provide better consumer protection to him and 3.3 million American Celiacs.

While Jax does not have T1D, we have learned that there is a significantly higher prevalence of Celiac Disease in Diabetes patients.¹³⁶ According to the University of Chicago, the estimated prevalence of Celiac Disease in patients with Type 1 Diabetes is approximately 6%.¹³⁷ Also see the comments of Brian Davis and family to the FDA’s Draft Guidance.¹³⁸

Figure 2 - Celiac Disease Sits at the Intersection of Food Allergies, Auto-immune Diseases & Digestive Diseases



¹³⁵ <https://www.whitehouse.gov/briefing-room/speeches-remarks/2022/03/01/remarks-of-president-joe-biden-state-of-the-union-address-as-delivered/>

¹³⁶ <https://celiac.org/about-celiac-disease/related-conditions/diabetes-and-celiac-disease>

¹³⁷ <https://www.uchicagomedicine.org/forefront/pediatrics-articles/are-pediatric-celiac-disease-and-type-1-diabetes-related>

¹³⁸ FDA Tracking Number 16v-04b4-4gs6, https://downloads.regulations.gov/FDA-2021-N-0553-1385/attachment_1.docx

B. What is Food Allergy? Adverse Reactions to Gluten in Celiacs Are Immune-Mediated.

According to the FDA, “A food allergy is caused by a naturally-occurring protein in a food or a food ingredient, which is referred to as an ‘allergen.’”¹³⁹ In answering the question, “What is Gluten?,” the NIH’s National Library of Medicine stated that Gluten is a food protein, and that Gluten Containing Grains include Wheat, Barley, Rye and Oats.¹⁴⁰ According to the NIAID’s (National Institute of Allergy and Infectious Disease’s) Sponsored Expert Panel found, “A food allergy is defined as an adverse health effect arising from a specific immune response that occurs reproducibly on exposure to a given food.”¹⁴¹

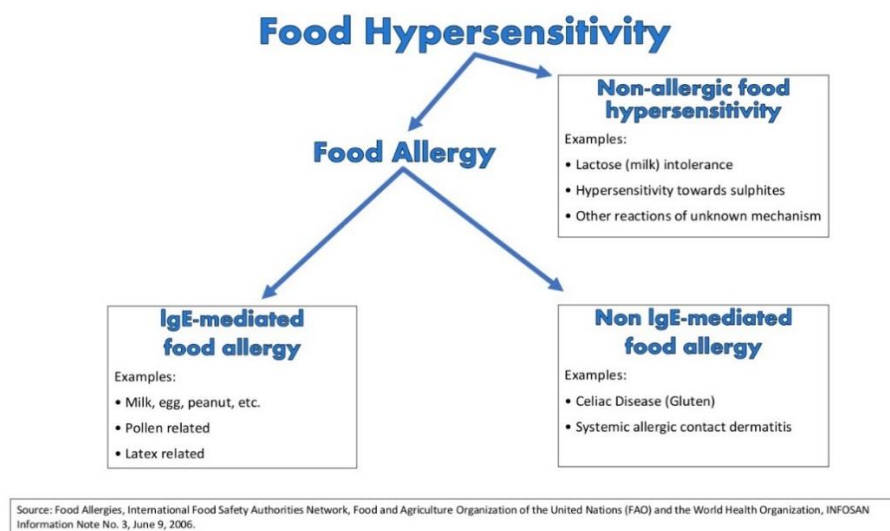
According to the FDA,

“Food allergy is a form of food hypersensitivity. Adverse reactions to food due to food hypersensitivity can be broadly grouped into reactions that are mediated by either immune mechanisms (food allergic reactions) or non-immune mechanisms (primarily food intolerances). Adverse reactions that are immune-mediated can be caused by:

- IgE-mediated mechanisms (e.g., IgE-mediated anaphylactic reaction to peanuts);
- **Non-IgE-mediated mechanisms (e.g., adverse reaction to gluten in the case of celiac disease);**
- Mixed immune mechanisms (e.g., eosinophilic gastroenteropathies); or
- Cell-mediated mechanisms (e.g., contact dermatitis).”¹⁴² (emphasis added)

C. What are Food Hypersensitivities?

Figure 3 - Food Hypersensitivities Range from Intolerances to Allergies: Food Allergies Are Much More Serious Than Food Intolerances, But Too Often Incorrectly Get Conflated with Food Intolerances or Voluntary Food Preferences (i.e., Gluten Free Lifestyle, Vegan, Vegetarian)



¹³⁹ <https://www.fda.gov/media/164194/download>

¹⁴⁰ <https://pubmed.ncbi.nlm.nih.gov/28244676/>

¹⁴¹ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4241964/pdf/nihms247178.pdf>

¹⁴² <https://www.fda.gov/media/157637/download>

D. What is Food Allergy? The Similarities and Differences Between Non-IgE-Mediated Mechanisms with Celiac Disease & Typical IgE-Mediated Mechanisms

Figure 4 - The Similarities and Differences Between Non-IgE-Mediated Mechanisms with Celiac Disease & Typical IgE-Mediated Mechanisms

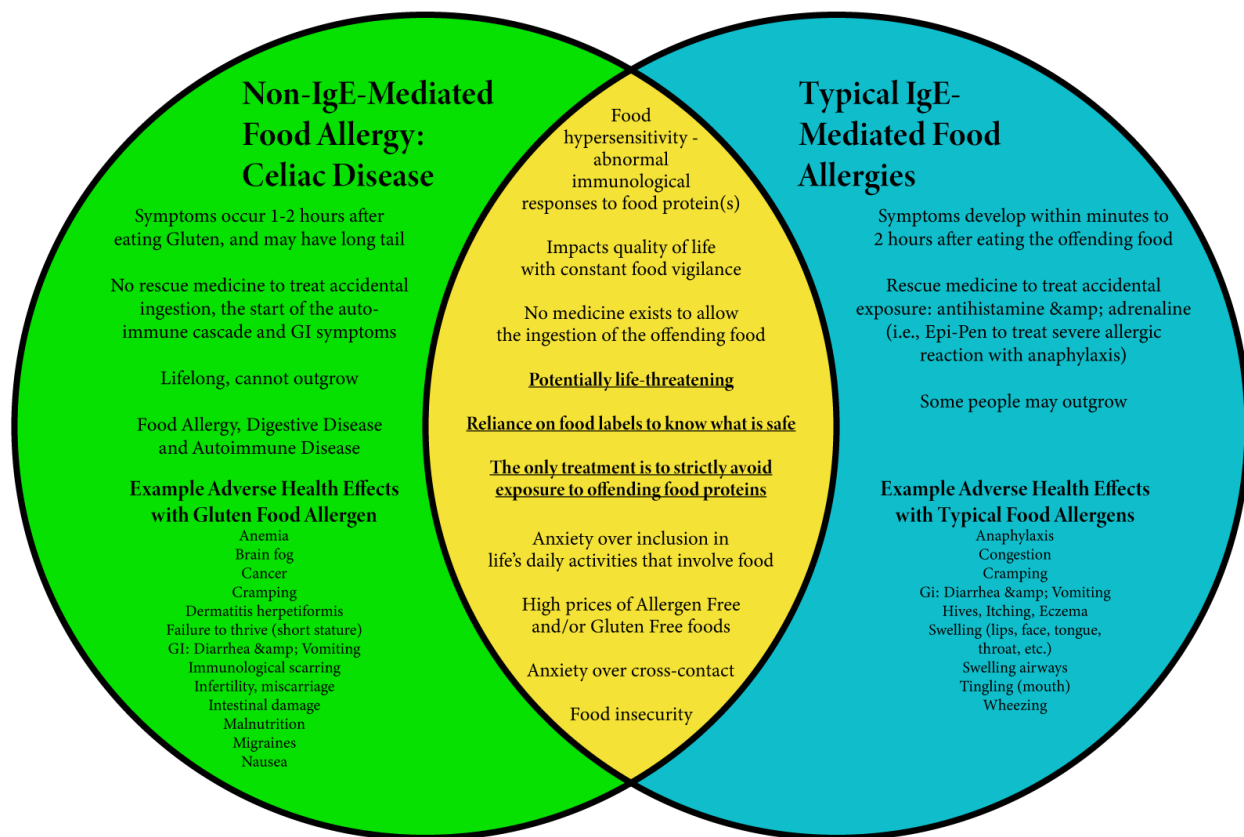


Figure 4 above illustrates the key near-peer similarities between food allergies that are Non-IgE-Mediated mechanisms with Celiac Disease (Gluten as a food allergen) and typical IgE-Mediated Mechanisms: potentially life-threatening, the only treatment is to strictly avoid the food allergen(s), and consumers' reliance on food labels to know what is safe to eat.

Importantly, unlike food allergies with IgE-Mediated mechanisms, there is no rescue medicine (i.e., adrenaline or antihistamine) to treat the accidental ingestion of Gluten and the start of the auto-immune cascade in food allergy with Non-IgE-Mediated mechanisms such as Celiac Disease. Additionally, those with a Non-IgE-Mediated food allergy to Gluten cannot outgrow their food allergy – Celiac is lifelong (until such time as a cure may be developed).¹⁴³

¹⁴³ This diagram graphic is intended to convey that Non-IgE-Mediated food allergy with Celiac Disease and typical IgE-Mediated food allergies are both really dangerous and deserve equal classification and treatment with respect to consumer protection with food labeling. The adverse health effects are listed in alphabetical order, and these health dangers are an illustrative, but not exhaustive list. This diagram will be discussed in greater detail herein, but it should be noted that this expands and updates information as was included in Table 2-1 in FDA's Draft Guidance Ref. 2.

While U.S. consumers' reactions to the top 9 Major Food Allergens (Milk, Eggs, Fish, Crustacean Shellfish, Tree Nuts, Peanuts, Wheat, Soybeans, and Sesame, collectively "Major Food Allergens") and Gluten vary, their consumer habits are the same -- they avoid purchasing foods that contain the allergen(s) that cause a potentially life-threatening immunological adverse reaction. Notwithstanding the foregoing, the key difference from a consumer protection standpoint is that under the Food Allergen Labeling and Consumer Protection Act of 2004, the labeling scheme for the top 9 Major Food Allergens in the U.S. is mandatory, but the labeling of Gluten is permissive. Wheat is required to be labeled, but Gluten is not. Gluten is found in Wheat, Barley, Rye and most Oats.¹⁴⁴ Just because something is Wheat free does not mean its Gluten Free.

E. Dietary Spectrum: Celiac Disease Food Allergy Must Be Treated as Seriously as IgE-Mediated Food Allergies; Celiac Disease Must Not Be Conflated with Gluten Intolerance (Non-Celiac Gluten Sensitivity) or a Voluntarily Chosen Gluten Free Lifestyle

Figure 5

	Food Preference	Food Intolerance (Sensitivity)	Food Allergy
Potentially Life Threatening	N/A	N/A	Potentially Life-Threatening & Life-Debilitating
Bodily System	N/A	Digestive System	Immune System
Consequence of Exposure	Disappointment	Discomfort	Danger
Diet Adherence	N/A	Discretionary	Strict: Lifetime, No Cheating & No Breaks
Examples	Gluten Free Lifestyle , Dairy Free, Keto, Low Carb, Vegan, Vegetarian, etc.	Gluten Intolerance (Non-Celiac Gluten Sensitivity) , Lactose Intolerance, Histamine Intolerance, etc.	Gluten , Milk, Eggs, Fish, Crustacean Shellfish, Tree Nuts, Peanuts, Wheat, Soybeans, Sesame, etc.
Symptoms	Annoyance, Bad Taste, Dissatisfaction, etc.	Cramping, Diarrhea, Gas, Heartburn, etc.	Anaphylaxis, Anemia, Brain Fog, Cancer, Congestion, Cramping, Diarrhea, Failure to Thrive, Immunological Scarring, Infertility, Intestinal Damage, Itching, Malnutrition, Migraines, Nausea, Swelling (lips, face, tongue, throat), Vomiting, Wheezing, etc.

¹⁴⁴ Gluten Containing Grains are Wheat, Barley, Rye and most Oats. Wheat is already codified as a Major Food Allergen in the U.S. As such, the focus of these Comments is on adding Barley, Rye and Oats. While Oats are naturally Gluten Free, it is instructive to read the 1999 Codex Criteria (See FDA Ref. 25) which stated, "The revised list of those foods and ingredients known to cause food allergies and intolerance and whose presence should always be declared was identified as the following: Cereals containing gluten (i.e. wheat, rye, barley, oats, spelt or their hybridized strains) and their products." Source: https://apps.who.int/iris/bitstream/handle/10665/42378/WHO_TRS_896.pdf . Also see 2021 FAO/WHO Expert Consultation as detailed herein (See FDA Ref. 45). Source: <http://www.fao.org/3/cb4653en/cb4653en.pdf>

F. About the Petitioners – What is Our Why?

Leslie Bari and Jon Bari are the parents of two children, Lexi (age 18) and Jax (age 10), and we live in Philadelphia. Lexi is a rising freshman at the Wharton School of the University of Pennsylvania, and she helped research and edit this Citizen Petition. Jax is a rising 5th grader who has Celiac Disease.

In August 2018, Jax, at age 5, was diagnosed through serology tests and an endoscopy at Children's Hospital of Philadelphia. Jax's endoscopy revealed Marsh 3 level (significant) damage to his small intestine which caused anemia and inhibited him from absorbing proper nutrients for growth and development. Serology was initially conducted because of failure to thrive.

Jax is intelligent, compassionate, athletic and mature beyond his years (which often times happens to kids who have chronic diseases). In September 2018, Jax started Kindergarten, and as he learned to read, he started with fairy tales and food labels.

Up until August 2018, we took our food freedom for granted. We enjoyed our food privilege of being able to eat whatever and wherever we wanted. Now, as parents of a child with Celiac Disease, our family has embraced its new normal. We are working to foster greater understanding of, accommodation for, and inclusion of those who suffer from Celiac Disease in life's daily activities that involve food. The required labeling of Gluten and referring to Gluten as a food allergen would be very helpful in terms of protecting Jax and 3.3 million Americans with Celiac.¹⁴⁵

Eating Ethos

Our patient advocacy goals are important to us because some day we want to be able to (in no order of importance):

- enjoy a worry-free meal with our family and eat without fear,
- have our family never have to worry about cross contact with Gluten, which is poison to our son's body,
- have our son not get violently ill if he gets Glutened (as has unfortunately happened on previous occasions),
- have our son enjoy the spontaneity of food in life's daily activities and special occasions that involve food,
- have our son always feel socially included at meal time with his friends and family by not having to eat special foods,
- have our son never experience food insecurity, and
- have us be able to rely on packaged food labels which are required to inform us if Gluten is in a product

We want to attain these goals so that our son can grow and develop fully, normally and in a healthy manner, physically and emotionally.

Without the mandatory labeling of Gluten legislation, our family (and 3.3 million Americans and their loved ones) continue to be at risk of unknowingly eating foods that contain Gluten. With the mandatory labeling of Gluten, it will help to ensure that food that our family purchases will be safe to eat for our son.

¹⁴⁵ <https://www.celiacjourney.com/about>

Until such time as other treatments and a cure are found, we hope others, including the FDA, will check their food privilege and understand that reasonable, common sense, attainable, scientifically-supported and low impact accommodations (which are already being done in more than 85 other countries with mandatory Gluten labeling) will foster a sense of diversity and inclusion to help those with allergic reactions to Gluten, especially children, safely and successfully navigate a Gluten filled world.

When Jax was diagnosed with Celiac, we were informed that the only available treatment was a strict Gluten Free diet for life, and that if he ate Gluten, he would get sick and continue to damage his small intestine. We intuitively thought of it in the context of a food allergy as most consumers and lay people do. As the Boston Globe reported about Dr. Alessio Fasano in 2015, “Fasano now gives his celiac patients *permission* to use the word allergy to describe their disease, since that will probably be taken more seriously.”¹⁴⁶ I loved that, but fast forward 7 years, and I think that we need much more than permission. In terms of consumer protection, the Celiac community would benefit greatly if the FDA and scientists would consistently refer to Celiac as a food allergy and Gluten as a food allergen. See article entitled, “Let’s Stop Gaslighting Gluten as a Second-Class Food Allergen & Celiac as Not a Food Allergy!”¹⁴⁷

When someone is buying food for Jax, preparing food for Jax, and/or serving food to Jax, we need to be able to clearly communicate to that person that Jax must avoid eating Gluten, since if he does eat Gluten, he will likely have an adverse health reaction. The simplest and most effective way to communicate this in Plain English is to say that Jax has a Food Allergy. This is the way that people organically talk about food when it can cause an adverse immunological reaction.

Unfortunately, in spite of our many precautions, Jax has been “glutened” at times through accidental ingestion of Gluten and that has resulted in him experiencing severe GI adverse reactions commensurate with foodborne illness (food poisoning),¹⁴⁸ and in addition, potential long-term complications including damage to his small intestine. In Summer 2021, Jax got violently ill when the chef at a restaurant thought a packaged food product was Gluten Free since it did not have Wheat labeled on it, but the food product did have unlabeled Gluten in it.^{149 150}

¹⁴⁶ <https://www.bostonglobe.com/magazine/2015/10/14/why-food-allergy-fakers-need-stop/PB6uN8NF3eLWFjXnKF5A9K/story.html>

¹⁴⁷ <https://www.celiacjourney.com/gaslighting>

¹⁴⁸ <https://www.cdc.gov/foodsafety/symptoms.html>

¹⁴⁹ See “Food Allergen Labeling And Consumer Protection Act of 2004 Questions and Answers”, Question 26, “What about food prepared in restaurants? How will I know that the food I ordered does not contain an ingredient to which I am allergic? FALCPA only applies to packaged FDA-regulated foods. However, FDA advises consumers who are allergic to particular foods to ask questions about ingredients and preparation when eating at restaurants or any place outside the consumer’s home.” <https://www.fda.gov/food/food-allergensgluten-free-guidance-documents-regulatory-information/food-allergen-labeling-and-consumer-protection-act-2004-questions-and-answers#>

¹⁵⁰ The CDC has estimated that fewer than half of the members of the restaurant staffs surveyed in 278 restaurants had received training on food allergies. Source: <https://www.cdc.gov/mmwr/volumes/66/wr/mm6615a2.htm> Taking that into account, it is suggested that even less understand about Celiac as a food allergy and Gluten as a food allergen, in part since Celiac often gets conflated with a voluntary Gluten Free diet.

That's one real world example of getting Glutened and why we need Gluten to be labeled on packaged foods!

Anecdotally, we can attest to the treatment burden of chronic disease, including the constant anxiety over cross contamination and inclusion of our son in life's numerous daily activities that involve food at home, at school and away from home (i.e., soccer practice, camp, celebrations, special events, vacation). We worry about every bite, every day! Period. Full stop.

It took over 24 months of Jax being on a strict Gluten Free diet for his serology tests to normalize including his Tissue Transglutaminase IgA (TTG-IgA). That said, on February 2, 2022, after having been on a strict Gluten Free diet for more than 3 years, Jax still needed to receive an iron infusion because he was still iron deficient anemic, and after doing multiple diagnostic and serologic tests, including hematology consults, the only reason that his team of physicians could provide was that this was as a result of his Celiac Disease and malabsorption issues.

The lived experience of those with Celiac who must avoid Gluten in their diet is the same as those who must avoid the top 9 major allergens, but for the fact that there is no comparable rescue medicine treatment available (i.e., antihistamine or adrenaline) to reverse the effects in the event of the ingestion of Gluten and the beginning of the autoimmune cascade that can cause a myriad of life-threatening conditions (cancer) as well as GI symptoms (similar to typical food allergies) and damage to the small intestine.

We stand for Jax, and as his voice, we demand action! We demand change! We seek progress! We seek more agency! We seek the labeling of Gluten on all packaged foods in the U.S., just like it is done in 85 countries around the world! We have traveled outside of the U.S. to countries where Gluten is required to be labeled, and we have experienced first-hand how the lived experience is fundamentally different for Celiacs in those countries which require that Gluten be declared on all packaged foods.

G. Our Lived Experience

As President Joe Biden said at the White House Conference on Hunger, Health, and Nutrition,

“[I]f a parent cannot feed a child, there's nothing else that matters for that parent. If you look at your child and you can't feed your child, what the hell else matters? I really mean it.”¹⁵¹ (emphasis added)

Unfortunately, that has been our lived the experience and that of many people with Celiac Disease as well as parents and caretakers of children with Celiac. This has been our experience when Jax has gotten “glutened” and violently ill like he recently was on April 1, 2023 in Denver, Colorado (see photo on the cover of this Citizen Petition of Jax Bari when he was incapacitated on the bathroom floor and in bed for two days).¹⁵² Eating out of the house is very challenging for Celiacs, and this impacts their quality of life on a daily basis. As such, this represents an example of how Celiacs have been systematically denied a full opportunity to participate in aspects of economic, social, and civic life.

¹⁵¹ <https://www.whitehouse.gov/briefing-room/speeches-remarks/2022/09/28/remarks-by-president-biden-at-the-white-house-conference-on-hunger-nutrition-and-health/#>

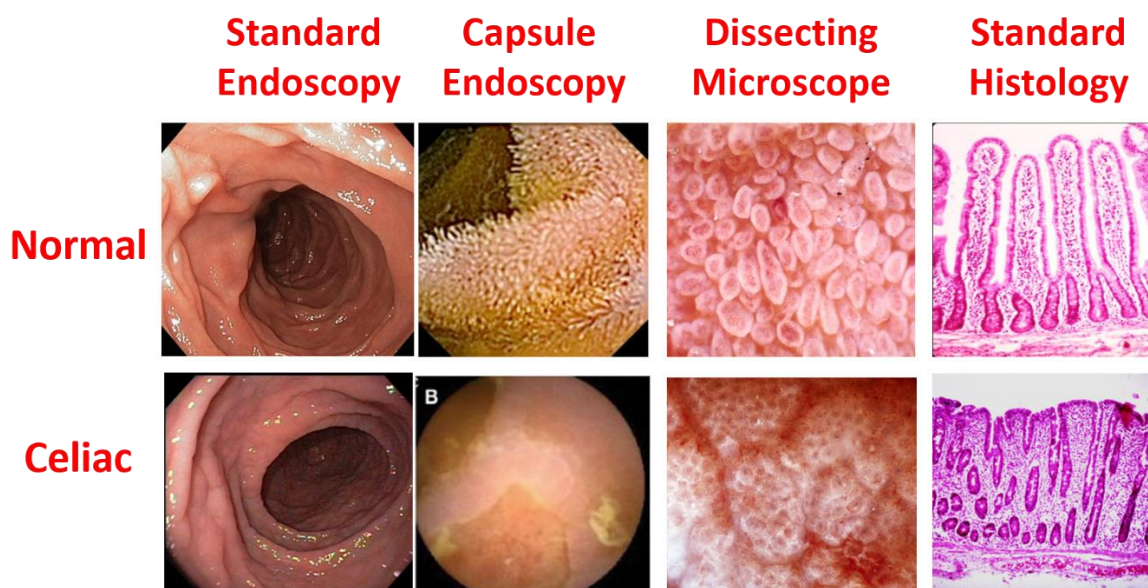
¹⁵² <https://www.instagram.com/p/CqnYV7lrRR4/>

One foundational way to help mitigate accidental glutenings and change societal views that Celiac is as serious as a peanut allergy, for example, is to require that Gluten be labeled as a Major Food Allergen.

To that end, we have been working on getting Gluten labeled as a Major Food Allergen for a number of years since Jax was diagnosed with Celiac right before he started Kindergarten in August 2018. Diagnosis was done through repeated serology tests and an endoscopy at Children's Hospital of Philadelphia.

Jax's intestine took years to heal, although he is still anemic, even after 5 (five) years of being on a strict Gluten Free diet. However, every time Jax accidentally gets Glutened (even just a crumb of Gluten is enough), he gets violently ill (like food poisoning) and the auto-immune cascade repeats and attacks his small intestine.

Figure 6 - Visualizing Villous Atrophy: Gluten Triggered Auto-Immune Cascade in Celiacs Damages the Small Intestine¹⁵³



Jax's story has helped put a face to people who are involuntarily Gluten Free due to Celiac Disease and their deeply personal struggles which many say they quietly face in the shadows. We have met so many amazing Celiac families which have had their health and quality of life impacted by adverse reactions to Gluten, as well as the food insecurity and anxiety that goes hand in hand with maintaining a strict Gluten Free diet, regardless of their socioeconomic status. However, it should be noted that families with low incomes, who have at least one member with Celiac Disease, are disproportionately impacted to an even greater extent in terms of food insecurity.

We are not lobbyists or lawyers; we are parents trying to feed our son and protect the Celiac community including about 730,000 children like Jax. While it is a labor of love, it is also an

¹⁵³ Graphic provided by Ciaran Kelly, MD, Medical Director, Celiac Center, BIDMC, Boston, Professor of Medicine & Co-founder, Celiac Research Program, Harvard Medical School, Used with Permission.

exhausting job to manage Celiac in addition to our day jobs. It should not be this hard to protect our children and that's why we are respectfully asking for help from President Biden, Secretary Becerra and Commissioner Califf!

H. Eating Without Fear – Jax's Story

On May 19, 2021, World News Tonight with David Muir, reported on Jax was featured on the America Strong segment and told David that,

“Eating without fear is our hope. Food insecurity happens every day for Celiacs because of the constant threat of cross contact with Gluten, 80% of foods have Gluten in them, the high price of Gluten Free food, the limited availability of Gluten Free food, and moreover Gluten is not required to be labeled on packaged foods in the U.S. like it is in Canada and across Europe.”¹⁵⁴

Out of the mouths of babes:



Jax Bari from Philadelphia, Pennsylvania (source: World News Tonight)

Please watch this amazing ABC News story featuring some of Jax's friends from around the country who also have Celiac and bravely shared their pediatric perspectives.¹⁵⁵ See www.CeliacJourney.com/abcnews.

Our family's story represents just one story from the millions of Americans who live with and/or care for someone with Celiac Disease who requires a strict Gluten Free diet with every bite, every day.

Jax is one of the many faces of Celiac Disease who can speak to the public health importance of food allergens other than the Major Food Allergens, and to that end, why we need Gluten to be named a Major Food Allergen and labeled on all packaged foods in the U.S. in order to adequately protect him and millions of others similarly situated.

¹⁵⁴ www.celiacjourney.com/abcnews

¹⁵⁵ www.celiacjourney.com/abcnews

As Mr. Muir reported in 2021, “Matthias Brockington, [a then] 10th grader from Norristown, Pennsylvania, and Ava, [a then] 6th grader from Maryland, said that the Gluten Free diet can be hard to follow -- especially with limited gluten-free options. ‘The only treatment for Celiac is a strict gluten-free diet which is pretty tough,’ said Brockington.”¹⁵⁶



Matthias Brockington from Norristown, Pennsylvania (source: World News Tonight)

“A gluten-free diet is really hard because not all packaged foods are clearly labeled as containing gluten. This makes it really hard to find safe, gluten-free food for people with celiac disease,” said Ava.¹⁵⁷



Ava, Maryland (source: World News Tonight)

¹⁵⁶ <https://abcnews.go.com/US/children-country-share-experiences-celiac-disease/story?id=77791565>

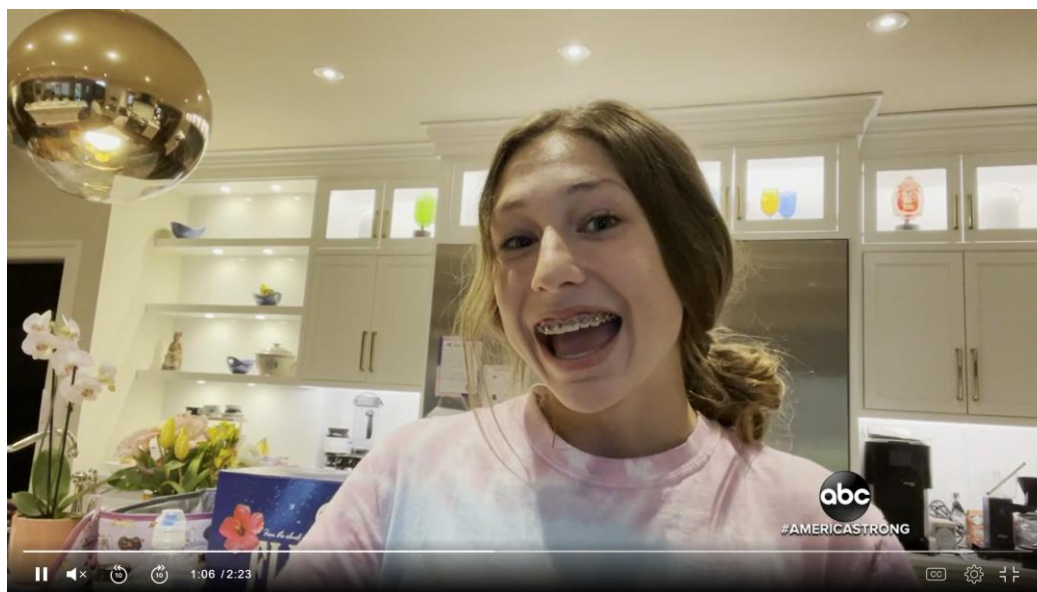
¹⁵⁷ <https://abcnews.go.com/US/children-country-share-experiences-celiac-disease/story?id=77791565>

“Maggy Beck, a third grader [in 2021] in Richmond, Virginia, said she struggles with being cautious around food. ‘I wish when I went to parties, I didn’t have to bring my own food and I didn’t have to worry about cross-contamination,’ said Maggy.”¹⁵⁸



Maggy Beck, Richmond, Virginia (source: World News Tonight)

Gianna C. commented on food labeling, “Hey David, I’m Gianna C., I’m in seventh [in 2021], and I live in Wyomissing Pennsylvania. My mom and I both have Celiac Disease and just staying on a gluten-free diet is not enough, we need to have gluten labeled as an allergen on processed foods in the United States just like it is in Europe and Canada.”¹⁵⁹



Gianna C. from Wyomissing, Pennsylvania (source: World News Tonight)

¹⁵⁸ <https://abcnews.go.com/US/children-country-share-experiences-celiac-disease/story?id=77791565>

¹⁵⁹ <https://abcnews.go.com/US/children-country-share-experiences-celiac-disease/story?id=77791565>

Everyone's experience is unique. We have met so many amazing Celiac families which have had their health and quality of life impacted by adverse reactions to Gluten, as well as the food insecurity and anxiety that goes hand in hand with maintaining a strict Gluten Free diet, regardless of their socioeconomic status. However, it should be noted that families with low incomes, who have at least one member with Celiac Disease, are disproportionately impacted to an even greater extent in terms of food insecurity.

I. Every Bite, Every Day! – There is No Break Ever from Celiac Disease!

There are no days off from Celiac! There is no cheating on the Gluten Free diet. The lifetime treatment burden of the Gluten Free diet is perceived by patients to be second only to end-stage renal disease, and by caregivers, comparable to caring for a patient with cancer. People with Celiac report a higher negative impact on their quality of life (treatment burden) than do people with Type 2 diabetes, congestive heart failure, hypertension, and inflammatory bowel disease.¹⁶⁰ Diagnosed patients report that they miss, on average, 23 days of work and school annually, resulting in excess utilization of our healthcare resources.¹⁶¹

We can attest to the treatment burden including the continuous concern over intestinal healing, proper nutrition, cross contact, and inclusion of our son in life's numerous daily activities that involve food at home, at school and away from home in daily life. Leslie is Jax's "advance team," and it is non-stop. Given that stress can trigger and/or exacerbate migraine attacks, our experience indicates that there is a connection between Leslie's diagnosis with chronic migraines in Summer 2018 and Jax's diagnosis with Celiac at that same time.¹⁶² Since July 2018, Leslie has had on average about 12 debilitating headache days per month.

We worry nonstop about how the accidental ingestion of Gluten could trigger Jax developing another autoimmune disease at some point since there is a significant association between Celiac Disease and 17 other disorders including Type 1 Diabetes, Crohn's disease, rheumatoid arthritis and ulcerative colitis.¹⁶³

¹⁶⁰ "Patient Perception of Treatment Burden is High in Celiac Disease Compared to Other Common Conditions," PMC, National Library of Medicine, National Institutes of Health, Shah, S., Akbari, M., Vanga, R., Kelly, C. P., Hansen, J., Theethira, T., Tariq, S., Dennis, M., & Leffler, D. A. (2014). *The American journal of gastroenterology*, 109(9), 13041311.

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4159418/> <https://doi.org/10.1038/ajg.2014.29> ; and "What is Celiac Disease?", Celiac Disease Foundation, <https://celiac.org/about-celiac-disease/what-is-celiac-disease/> ; <https://www.beyondceliac.org/invisible-illness-infographic/> .

¹⁶¹ Testimony of Marilyn G. Geller, CEO, Celiac Disease Foundation (Los Angeles, CA), to the U.S. House of Representatives Committee on Appropriations, Subcommittee on Labor, Health and Human Services, Education, and Related Agencies, April 9, 2019, <https://celiac.org/april-2019-congressional-testimony-by-ceo-marilyn-g-geller/>.

¹⁶² Leslie's migraines have continued through to the present, in spite of being under the continuous care and treatment of neurologists specializing in migraines.

¹⁶³ <https://www.allergicliving.com/2020/02/06/celiac-disease-and-its-sister-conditions/> ; <https://celiac.org/about-celiac-disease/related-conditions/autoimmune-disorders/#> ; and <https://www.cureceliacdisease.org/faq/what-other-autoimmune-disorders-are-typically-associated-with-those-who-have-celiac-disease/>

By declaring that Gluten must be labeled on all packaged foods in the U.S., the FDA would help to mitigate the treatment burden and food insecurity that 3.3 million American Celiacs, their loved ones, parents and caretakers, face with every bite, every day!

In addition, our Citizen Petition to label Gluten as a Major Food Allergen has been informed in part by many of the 1,576 thoughtful comments on labeling Gluten (and Celiac) submitted to the FDA in 2022 in response to the FDA's Draft Guidance.¹⁶⁴

J. It Takes a Village – 1,576 Comments Submitted to the FDA on Labeling Gluten

In addition to the comments to the FDA's Draft Guidance summarized above, by August 17, 2022 when the comment period closed, there were a total of 1,903 comment submissions on the FDA's Draft Guidance.¹⁶⁵ Of those, 1,576 comments discussed Celiac Disease and/or Gluten.¹⁶⁶ In other words, 82.8% of the comments submitted to the FDA were about the unmet need for labeling Gluten on all packaged foods as a Major Food Allergen in the United States.

To the best of our knowledge, there were no automated systems in place to help people generate form letter comments to the FDA. From a comprehensive review of many of the submitted comments, there were very heartfelt and personal lived experiences shared. We worked with various national advocacy groups, physician scientists and individuals on a real grassroots effort¹⁶⁷ to help generate the 1,576 comments including from:

- Bari Consulting Group, Celiac Journey and Gluten Free Finds, August 16, 2022¹⁶⁸ (“Bari Comments”) See Citizen Petition Exhibit 6.
- Beyond Celiac, August 12, 2022.¹⁶⁹
- Celiac Community Foundation of Northern California, August 17, 2022.¹⁷⁰
- Gluten Free Watchdog, May 9, 2022.¹⁷¹

¹⁶⁴ <https://www.regulations.gov/docket/FDA-2021-N-0553/comments?filter=celiac>

¹⁶⁵ <https://www.regulations.gov/docket/FDA-2021-N-0553/comments>

¹⁶⁶ <https://www.regulations.gov/docket/FDA-2021-N-0553/comments?filter=celiac>

¹⁶⁷

[https://twitter.com/GFWatchdog/status/1560633576529752065?ref_src=twsrc%5Etfw%7Ctwcamp%5Etweetembed%7Ctwterm%5E1560633576529752065%7Ctwgr%5Edcb3ca6a9147117802409ba4a1780ea2cb3b8210%7Ctwcon%5Es1_&ref_url=https%3A%2F%2F36aae226-db3c-4195-a692-](https://twitter.com/GFWatchdog/status/1560633576529752065?ref_src=twsrc%5Etfw%7Ctwcamp%5Etweetembed%7Ctwterm%5E1560633576529752065%7Ctwgr%5Edcb3ca6a9147117802409ba4a1780ea2cb3b8210%7Ctwcon%5Es1_&ref_url=https%3A%2F%2F36aae226-db3c-4195-a692-21ab2322143d.usrfiles.com%2Fhtml%2Fdb9376e69cfa487ea0fa0b912ae51a4f_v1.html)

[21ab2322143d.usrfiles.com%2Fhtml%2Fdb9376e69cfa487ea0fa0b912ae51a4f_v1.html](https://twitter.com/GFWatchdog/status/1560633576529752065?ref_src=twsrc%5Etfw%7Ctwcamp%5Etweetembed%7Ctwterm%5E1560633576529752065%7Ctwgr%5Edcb3ca6a9147117802409ba4a1780ea2cb3b8210%7Ctwcon%5Es1_&ref_url=https%3A%2F%2F36aae226-db3c-4195-a692-21ab2322143d.usrfiles.com%2Fhtml%2Fdb9376e69cfa487ea0fa0b912ae51a4f_v1.html)

¹⁶⁸ FDA Comment ID: FDA-2021-N-0553-1584, FDA Tracking Number l6w-qe9m-4tjy, https://downloads.regulations.gov/FDA-2021-N-0553-1584/attachment_1.pdf. Note that the authors of this Citizen Petition and the Bari Comments are the same, and while there is overlap between the documents, each document is separate.

¹⁶⁹ FDA Comment ID: FDA-2021-N-0553-1353, FDA Tracking Number: l6q-v6ic-9kfi, https://downloads.regulations.gov/FDA-2021-N-0553-1353/attachment_1.pdf

¹⁷⁰ FDA Comment ID: FDA-2021-N-0553-1691, FDA Tracking Number: l6x-3son-9p1o, https://downloads.regulations.gov/FDA-2021-N-0553-1691/attachment_1.pdf

¹⁷¹ FDA Comment ID: FDA-2021-N-0553-0179, FDA Tracking Number l2u-t68j-qa01, https://downloads.regulations.gov/FDA-2021-N-0553-0179/attachment_1.pdf

- Dr. Amanda Muir, August 8, 2022.¹⁷² Dr. Muir is a Pediatric Gastroenterologist in the Division of Gastroenterology, Hepatology and Nutrition at the Children’s Hospital of Philadelphia.¹⁷³
- National Celiac Association, June 14, 2022.¹⁷⁴
- Dr. Arunjot Singh, August 17, 2022.¹⁷⁵ Dr. Singh is Assistant Professor of Clinical Pediatrics, Co-Director, Children's Hospital of Philadelphia's Center for Celiac Disease, Division of Gastroenterology, Hepatology & Nutrition, Perelman School of Medicine - University of Pennsylvania.
- University of Chicago Celiac Disease Center, August 3, 2022.¹⁷⁶

K. Celiac Disease Foundation Applauds Jax Bari’s Advocacy to Get Gluten Labeled

In a July 2023 article entitled “Celiac Disease Patient and Advocate Jax Bari Carries Cause to the White House,” the Celiac Disease Foundation celebrated Jax’s advocacy,

“Jax Bari, now 10 years old, has been a strong advocate for celiac disease since his diagnosis in August of 2018. Jax and his family have dedicated much energy to raising awareness of celiac disease and promoting the need for alternative treatments to the gluten-free diet and a cure for celiac disease. Jax has also been advocating to require the labeling of gluten on all packaged foods in the US and increasing government funding for celiac disease research.

As part of his work to raise awareness for celiac disease on a national level, Jax met with President Biden to request that gluten be labeled. Jax was then invited to share his lived experience and labeling request with the White House Domestic Policy Council. Additionally, Jax met with senior leadership from the U.S. Food and Drug Administration and senior staff from the office of Department of Health and Human Services (HHS) Secretary Xavier Becerra.

Jax was joined in his meetings by Dr. Virginia Stallings, one of the world’s foremost

¹⁷² FDA Comment ID: FDA-2021-N-0553-1587, FDA Tracking Number l6w-qnl1-geu8, https://downloads.regulations.gov/FDA-2021-N-0553-1587/attachment_1.pdf

¹⁷³ Dr. Muir is a physician-scientist with a laboratory studying mechanisms of inflammation in Non-IgE mediated food allergy (specifically eosinophilic gastrointestinal disorders), and she has a clinical practice dedicated to taking care of children with these disorders. According to Dr. Muir’s FDA Comments, “Eosinophilic esophagitis, or EoE, is a chronic allergic disease that affects pediatric patients and adults alike. In the setting of exposure to foods that are ubiquitous in the American diet, most commonly milk and gluten, an inflammatory process occurs in the esophagus leading to esophageal damage and narrowing. Celiac Disease is an autoimmune disorder in which exposure to gluten containing foods, causes, ‘face potentially life-threatening illnesses if they eat gluten, typically found in breads, cakes, cereals, pastas, and many other foods... There is no cure for celiac disease and the only way to manage the disease is to avoid eating gluten.’ Taken together, these two entities, Celiac Disease and EoE represent non-IgE mediated food allergies that would greatly benefit from specific gluten labeling.”

¹⁷⁴ FDA Comment ID FDA-2021-N-0553-0822, FDA Tracking Number: l4e-cf9x-ka7n , https://downloads.regulations.gov/FDA-2021-N-0553-0822/attachment_1.pdf

¹⁷⁵ FDA Comment ID: FDA-2021-N-0553-1681, FDA Tracking Number: l6x-2tjb-tdx0, https://downloads.regulations.gov/FDA-2021-N-0553-1681/attachment_1.pdf

¹⁷⁶ FDA Comment ID: FDA-2021-N-0553-1083, FDA Tracking Number l6d-sfof-noog

experts on food allergies who is a board-certified nutrition pediatrician, Professor of Pediatrics, and Director of the Nutrition Center at the Childrens Hospital of Philadelphia, where Jax has been treated for Celiac Disease since 2018.

Congratulations to Jax and his family for continuing to raise awareness on these important topics! **With advocates like Jax supporting celiac disease patients across the country, our community will receive the federal support it desperately needs.**¹⁷⁷ (emphasis added)

L. A Mom's Poetic Plea: What Getting Glutened Looks Like!

In addition to the cover photo on this Citizen Petition of Jax Bari after he was glutened on April 1, 2023, it is instructive to note Jax is far from alone. On June 18, 2022, Britney Asbel posted the following on Facebook about her son (age 5 in 2022) with Celiac.



177 <https://celiac.org/about-the-foundation/featured-news/2023/07/celiac-disease-patient-and-advocate-jax-bari-carries-cause-to-the-white-house/>

“This.
This right here.
This is celiac.
Celiac Disease.
Two simple words.

One complex disease.
No gluten.
Simple?
It should be.
It isn't.

No gluten.
Label reading.
Constant questioning.
Cross contamination.
Can we eat here?
Do we trust them?
Is this labeled correctly?

No gluten.
Ever.
Not even a crumb.
This is celiac disease.
Accidents.
Accidental glutening.
Glutening.
Belly pain.
Nausea.
Vomiting.
Heaving.
Over and over again.
For hours.
Laying on the bathroom floor.
Falling asleep between episodes.
Dark circles under the eyes.
Pale skin.
Distended abdomen.
And more.

For us.
It's a 5 year old warrior.
It's a 5 year old who lives to the fullest.
It's a 5 year old who takes these accidental glutening like a champ.
It's a 5 year old who's a super celiac kid.
Fight on.

Also, 🤦 Vans Waffles for all the boxes looking so similar. Our family who is always so careful made the mistake of grabbing one gf box and one regular box. Half a waffle and hours of pain.”¹⁷⁸

¹⁷⁸ <https://www.facebook.com/photo/?fbid=10161476598607289&set=a.10150292089997289> (as publicly posted on Facebook, and as used with written permission by the person who published it, permission on file with author of this Citizen Petition).

IV. Labeling of Gluten as a Major Food Allergen Comports with Criteria & Conclusions from International Food Safety Authorities & Experts, Including from the FDA

“The idea that you can get up here and talk about what you know -- what the evidence, what the science is -- and know that’s it, let the science speak.”¹⁷⁹

-- Dr. Anthony Fauci

“Although many patients are convinced of the importance of food in both causing and relieving their problems, many doctors’ knowledge of nutrition is rudimentary. Most feel much more comfortable with drugs than foods, and the ‘food as medicine’ philosophy of Hippocrates has been largely neglected.”¹⁸⁰

-- Richard Smith, Editor, BMJ

A. Overview: Follow the Science & Data

The FDA’s Draft Guidance and moreover the current consumer protection law, the Food Allergen Labeling and Consumer Protection Act of 2004, appear to be inconsistent with the conclusions of international food safety authorities and expert committees comprised of scientists, regulators, physicians, clinicians and risk managers from academia, government and the food industry including:

- **Joint Food and Agriculture Organization of the United Nations/World Health Organization Expert Committee on Food Additives.** Evaluation of certain food additives and contaminants: fifty-third report of the Joint FAO/WHO Expert Committee on Food Additives. 2000. WHO Technical Report Series 896. World Health Organization, Geneva (“1999 FAO/WHO Expert Consultation”; also referred to as the “1999 Codex Criteria” as detailed in the FDA’s Draft Guidance and cited as “FDA Ref. 25”).¹⁸¹ See Citizen Petition Exhibit 3.
- **Food and Agriculture Organization of the United Nations/World Health Organization.** “Summary report of the Ad hoc Joint FAO/WHO Expert Consultation on Risk Assessment of Food Allergens. Part 1: Review and validation of Codex priority allergen list through risk assessment.” 2021 (“2021 FAO/WHO Expert Consultation”; also referred to as “FDA Ref. 45” in the FDA’s Draft Guidance).¹⁸² The 2021 FAO/WHO Expert Consultation was chaired by the FDA’s Dr. Lauren Jackson. See Citizen Petition Exhibit 2. In 2022, the 2021 FAO/WHO Expert Consultation’s complete report was published, “FAO and WHO 2022 Risk Assessment of Food Allergens. Part 1 - Review and Validation of Codex Alimentarius Priority Allergen List Through Risk Assessment. Meeting Report. Food Safety and Quality Series No. 14, Rome.” (“2022 FAO/WHO Expert Consultation”).¹⁸³ See Citizen Petition Exhibit 7.

¹⁷⁹ <https://www.nytimes.com/2021/01/21/us/politics/fauci-trump-biden-coronavirus.html>

¹⁸⁰ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC318470/>

¹⁸¹ https://apps.who.int/iris/bitstream/handle/10665/42378/WHO_TRS_896.pdf (Annex 4, pages 124-128)

¹⁸² <http://www.fao.org/3/cb4653en/cb4653en.pdf>

¹⁸³ <http://www.fao.org/3/cb9070en/cb9070en.pdf>

2021 FAO/WHO Expert Consultation, Chaired by the FDA's Dr. Lauren Jackson (top left)¹⁸⁴



The 2021 FAO/WHO Expert Consultation was comprised of 20 (twenty) “scientists, regulators, physicians, clinicians and risk managers from academia, government and the food industry were selected to participate in the first meeting of the FAO/WHO Expert Consultation on Risk assessment of Food Allergens.”¹⁸⁵ These “experts” from around the world included four experts from the United States, two of whom work for the FDA:

- **Dr. Joseph Baumert**, Professor and Director of the Food Allergy Research and Resource Program (FARRP), Department of Food Science and Technology at the University of Nebraska-Lincoln;¹⁸⁶ (Pictured in top row of photograph, 3rd from left)
- **Dr. Lauren Jackson**, Chief, Process Engineering Branch, Food and Drug Administration. Division of Processing Science & Technology, Institute for Food Safety & Health, who served as Chairperson of the Ad hoc Joint FAO/WHO Expert Consultation on Risk Assessment of Food Allergens (FDA Ref. 45);¹⁸⁷ (Pictured in top row of photograph, 1st person on left)
- **Dr. Stefano Luccioli**, Medical Officer and Allergy Specialist at the Center for Food Safety and Applied Nutrition of the Food and Drug Administration, and Board-certified doctor in allergy/immunology -- sees patients at the General Internal Medicine clinic at MedStar Georgetown University Hospital in Washington, D.C.;¹⁸⁸ and Chairperson of Ad hoc Joint FAO/WHO Expert Consultation on Risk Assessment of Food Allergens Part 3: Review and establish precautionary labelling in foods of the priority allergens¹⁸⁹ (Pictured 2nd row of photograph, 4th person from left).
- **Dr. Stephen Taylor**, Professor and Founding Director (Retired) of the Food Allergy Research and Resource Program (FARRP), Department of Food Science and Technology at the University of Nebraska-Lincoln.¹⁹⁰ Dr. Taylor was also one of six scientists who served

¹⁸⁴ <https://www.fao.org/food-safety/news/news-details/fr/c/1398460/>

¹⁸⁵ <http://www.fao.org/3/cb4653en/cb4653en.pdf>

¹⁸⁶ <https://farrp.unl.edu/fss/joe-baumert>

¹⁸⁷ <http://www.fao.org/3/cb4653en/cb4653en.pdf>

¹⁸⁸ <https://www.medstarhealth.org/doctors/stefano-luccioli-md>

¹⁸⁹ <https://cdn.who.int/media/docs/default-source/food-safety/jemra/3rd-allergen-summary-report-13dec2021.pdf>

¹⁹⁰ <https://farrp.unl.edu/fss/staylor>

on the Ad Hoc Panel on Food Allergens met in Geneva, Switzerland in February 1999 to provide advice to the Joint FAO/WHO Expert Committee on Food Additives about criteria for labelling food allergens. Their treatise was memorialized in the 1999 FAO/WHO Expert Consultation; also referred to as the “1999 Codex Criteria” as detailed in the FDA’s Draft Guidance and cited as “FDA Ref. 25”.¹⁹¹ (Pictured in bottom row of photograph, 2nd person from left).

In addition to these experts, the 2021 FAO/WHO Expert Consultation was comprised of 10 (ten) “resource persons” including two from the United States who work for the USDA and FDA:

- **Dr. J. Emilio Esteban**, Chief Scientist of the U.S. Department of Agriculture (USDA) Food Safety and Inspection Service (FSIS), who serves as the Codex Committee Chairperson from the United States;¹⁹² and
- **Dr. Douglas Balentine**, Senior Science Advisor, Global Nutrition Policy Center for Food Safety and Applied Nutrition, FDA, who serves as the U.S. Delegate on Food Labeling on the Codex Committee.¹⁹³

B. Summary Chart of the “Big 8” Food Allergens from the 1999 Codex Criteria, FALCPA and the 2021 Ad Hoc Joint FAO/WHO Expert Consultation

Figure 7

	Food Allergen	Prevalence of Food Allergy in the U.S.	“The Big 8” - 1999 Codex Criteria	Top 8 Major Food Allergens - FALCPA 2004	2021 FAO/WHO Expert Consultation, May 2021
1	Cereals Containing Gluten	3.3+ million	X (Wheat, Barley, Rye, Oats)		X (i.e., Wheat and other Triticum species, rye and other Secale species, Barley and other Hordeum species and their hybridized strains) See note on Oats
2	Crustacea (Shellfish)	8.2 million	X	X	X
3	Egg	2.6 million	X	X	X
4	Fish (fin)	2.6 million	X	X	X
5	Milk	6.1 million	X	X	X
6	Peanuts	6.1 million	X	X	X
7	Sesame	0.7 million		X (as of 1/1/23)	X
8	Soybeans	1.9 million	X	X	
9	Tree Nuts	3.9 million	X	X	X (Almond, Cashew, Hazelnut, Pecan, Pistachio and Walnut)
10	Wheat	2.4 million		X	

¹⁹¹ <https://apps.who.int/iris/handle/10665/42378>

¹⁹² <https://www.fsis.usda.gov/contactus/j-emilio-esteban>

¹⁹³ <https://www.usda.gov/sites/default/files/documents/us-codex-program-officials.pdf> ; and <https://www.fsis.usda.gov/contactus/j-emilio-esteban>

C. 1999 Codex Criteria, FAO/WHO Expert Consultation – Label Gluten as Priority/Major Food Allergen

For example, the 1999 FAO/WHO Expert Consultation determined:

“The revised list of those foods and ingredients known to cause food allergies and intolerance and whose presence should always be declared was identified as the following: cereals containing gluten (i.e. wheat, rye, barley, oats, spelt or their hybridized strains) and their products; Crustacea and products of these; Egg and egg products; Fish and fish products; Peanuts, soybeans, and products of these; Milk and milk products (lactose included); Tree nuts and nut products; and Sulfites in concentrations of 10 mg/kg or more.”¹⁹⁵ (emphasis added)

According to the FAO and WHO 2022 Risk Assessment of Food Allergens. Part 1 - Review and validation of Codex Alimentarius Priority Allergen List Through Risk Assessment. Meeting Report. Food Safety and Quality Series No. 14, “This list has been known informally as the “Big 8” food allergens as they are the most common and are responsible for most allergic reactions, although about 170 foods have been reportedly implicated in allergic reactions (Boyce *et al.*, 2011; Hefle, Nordlee and Taylor, 1996).”¹⁹⁶

D. 2021 FAO/WHO Expert Consultation – Label Gluten as Priority/Major Food Allergen Based on the Criteria of Prevalence, Severity & Potency

The 2021 FAO/WHO Expert Consultation, which was chaired by the FDA’s Dr. Lauren Jackson, Chief, Process Engineering Branch, Division of Processing Science & Technology, Institute for Food Safety & Health, determined:

“The Expert Committee determined that only foods or ingredients that cause immune-mediated hypersensitivities such as IgE-mediated food allergies and coeliac”¹⁹⁷

¹⁹⁴ A) https://apps.who.int/iris/bitstream/handle/10665/42378/WHO_TRS_896.pdf (Annex 4, pages 124-128); <http://www.fao.org/3/cb4653en/cb4653en.pdf> . B) <https://grants.nih.gov/grants/guide/notice-files/NOT-AI-22-004.html> ; Other Major Food Allergens: <https://www.foodallergy.org/media/1012/download?attachment> Warren CM, Chadha AS, Sicherer SH, Jiang J, Gupta RS. Prevalence and Severity of Sesame Allergy in the United States. JAMA Network Open 2019; 2(8):e199144. doi:10.1001/jamanetworkopen.2019.9144. C) Gupta RS, Warren CM, Smith BM, Jiang J, Blumenstock JA, Davis MM, Schleimer RP, Nadeau KC. Prevalence and Severity of Food Allergies Among US Adults. JAMA Network Open 2019; 2(1):e185630.doi:10.1001/jamanetworkopen.2018.5630. <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2720064> #: and Gupta RS, Warren CM, Smith BM, Blumenstock JA, Jiang J, Davis MM, Nadeau KC. The Public Health Impact of Parent-Reported Childhood Food Allergies in the United States. Pediatrics 2018; 142(6):e20181235. D) Oats - https://downloads.regulations.gov/FDA-2021-N-0553-1584/attachment_1.pdf (footnote 10)

¹⁹⁵ https://apps.who.int/iris/bitstream/handle/10665/42378/WHO_TRS_896.pdf

¹⁹⁶ <https://www.fao.org/3/cb9070en/cb9070en.pdf>

¹⁹⁷ “Coeliac” is the Greek spelling of Celiac which is used in some parts of the world.

[Celiac] disease should be included on the list of foods and ingredients included in section 4.2.1.4 of the GSLPF [General Standard for the Labelling of Prepacked Foods],”¹⁹⁸ and that the GSLPF list includes Gluten.

“The Committee identified **prevalence** of the immune-mediated hypersensitivity to a specific food, **severity** (i.e. proportion of severe objective reactions to a food/ingredient *such as anaphylaxis*), and the **potency** of food/ingredient (i.e. the amount of the food/ingredient required to cause objective symptoms) as the three key criteria that should be used to establish the priority allergen list. Subgroups of the Expert Committee were established to review the literature on the prevalence, severity and potency of immune-mediated hypersensitivity of each food currently on the GSLPF list (**cereals containing gluten and products of these**; crustacea and products of these; eggs and egg products; fish and fish products; peanuts, soybeans and products of these; milk and milk products; tree nuts and nut products;), as well as other foods found on priority allergen lists established in individual countries or regions (e.g. mollusks, mustard, celery, sesame, buckwheat, lupin, and others).

Based on systematic and thorough assessments which used all three criteria (prevalence, severity and potency), the Committee recommended that the following should be listed as priority allergens: Cereals containing gluten (i.e., wheat and other Triticum species, rye and other Secale species, barley and other Hordeum species and their hybridized strains), crustacea, eggs, fish, milk, peanuts, sesame, specific tree nuts (almond, cashew, hazelnut, pecan, pistachio and walnut).”^{199 200} (emphasis added)

Criteria: Prevalence, Severity & Potency

While the 1999 FAO/WHO Expert Consultation and the 2021 FAO/WHO Expert Consultation are cited as sources in the FDA’s Draft Guidance (FDA Ref. 25 and FDA Ref. 45 respectively), the FDA’s Draft Guidance omits key findings by the “scientists, regulators, physicians, clinicians, and risk managers from academia, government and the food industry,” and their informed recommendations (“based on systematic and thorough assessments which used all three criteria (prevalence, severity and potency)” to always declare (label) Gluten on food product labels in order to provide consumer protection for the Celiac community to whom ingesting Gluten is eating poison, life-debilitating and potentially life-threatening.

To unpack this further, when the experts analyzed the “severity” criteria, they focused on the “proportion of severe objective reactions to a food/ingredient *such as anaphylaxis*,” but not limited solely to anaphylaxis. The FDA and the 3.3 million American Celiacs would be better protected if the FDA adopted this more inclusive and accurate definition of severity to not intentionally other Celiacs and gaslight Gluten as a second-class allergen. In other words,

¹⁹⁸ <http://www.fao.org/3/cb4653en/cb4653en.pdf>

¹⁹⁹ “Due to the lack of data on prevalence, severity and/or potency, or due to regional consumption of some foods, the Committee recommended that some of the allergens, ... oats, ... should not be listed as global priority allergens but [Oats] may be considered for inclusion on priority allergen lists in individual countries.” <http://www.fao.org/3/cb4653en/cb4653en.pdf> While Oats are naturally Gluten Free, cross contamination with Gluten is for all intents and purposes inevitable. See Section IV.G. in this Citizen Petition entitled, “Oats Must Be Included by the FDA as a Gluten Containing Grain and Thus Declared on All Food Packages.”

²⁰⁰ <http://www.fao.org/3/cb4653en/cb4653en.pdf>

severity of reaction for Celiacs with Gluten ingestion includes, but is not limited to: anemia, cancer, failure to thrive, heart disease, immunological scarring, intestinal damage, malnutrition, osteoporosis, etc.

The global adherence to and the implementation of the 1999 FAO/WHO Expert Consultation and 2021 FAO/WHO Expert Consultation can be seen in how more than 85 countries worldwide require that Gluten be labeled on all packaged foods, according to the map and chart produced by the Food Allergy Research and Resource Program at the University of Nebraska-Lincoln.²⁰¹

E. Gluten Is Required to Be Labeled as a Major Food Allergen on Packaged Foods in More than 85 Countries Worldwide (shaded in red), Not Including the United States

Figure 8



Source: Food Allergy Research and Resource Program at the University of Nebraska-Lincoln²⁰²

²⁰¹ According to the University of Nebraska-Lincoln, the following countries require that Gluten be labeled on packaged foods: Anguilla, Antigua and Barbados, Argentina, Australia, Austria, Bahamas, Barbados, Belarus, Belgium, Belize, Bermuda, Bolivia, Brazil, British Virgin Islands, Bulgaria, Canada, Cayman Island, Chile, China, Colombia, Costa Rica, Croatia, Cuba, Cyprus, Czech Republic, Denmark, Dominica, Egypt, El Salvador, Estonia, Fiji, Finland, France, Germany, Greece, Grenada, Guatemala, Guyana, Haiti, Honduras, Hong Kong, Hungary, India, Ireland, Italy, Jamaica, Kazakhstan, Kuwait, Latvia, Lithuania, Luxembourg, Malawi, Malaysia, Malta, Mexico, Montserrat, Morocco, Netherlands, New Zealand, Nicaragua, Oman, Philippines, Poland, Portugal, Qatar, Romania, Russia, Saint Lucia, Saudi Arabia, Singapore, Slovakia, Slovenia, Spain, St. Kitts and Nevis, St. Vin. and Grenada, Suriname, Sweden, Thailand, Trinidad and Tobago, Turkey, Turks and Caicos Island, Ukraine, United Arab Emirates, United Kingdom, Venezuela, Vietnam, and Yemen. Source: <https://farrp.unl.edu/IRChart>

²⁰² <https://farrp.unl.edu/IRChart>

F. Dr. Virginia Stallings, Professor of Pediatrics and Director of the Nutrition Center at the Children’s Hospital of Philadelphia Has Called for Gluten to Be Labeled

We agree with the comments that Dr. Virginia A. Stallings, a board-certified nutrition pediatrician, Professor of Pediatrics and Director of the Nutrition Center at the Children’s Hospital of Philadelphia. Dr. Stallings was also the Editor and Chair of the National Academies of Sciences, Engineering, and Medicine, Committee on Food Allergies which published the seminal work: “Finding a Path to Safety in Food Allergy: Assessment of the Global Burden, Causes, Prevention, Management and Public Policy” (“Finding a Path”).²⁰³ Finding a Path is a 574 page report was published by the National Academies Press, 2016 and cited as FDA Ref. 2 in the FDA’s Draft Guidance (“FDA Ref. 2”)²⁰⁴ to narrowly and incorrectly define food allergen and food allergy.²⁰⁵

Even though the Federally funded FDA Ref. 2 expressly stated that “Food allergy has two key classifications: immunoglobulin E (IgE)-mediated or non-IgE-mediated” (page 4),²⁰⁶ the FDA’s Draft Guidance defined Food Allergen based on two primary references that expressly excluded Celiac Disease in their scope of work and stated, “do not discuss celiac disease,”²⁰⁷ as well as Celiac is “not covered in this report because they were beyond the scope of the statement of task.”²⁰⁸

It is absolutely maddening that the FDA has othered the consumer protection needs of the Celiac community by lumping Celiac and lactose intolerance together in the FDA’s Draft Guidance,

“Immune-mediated mechanisms that are not IgE-mediated (such as mechanisms associated with celiac disease and contact dermatitis), and mechanisms that are not immune-mediated (such as lactose intolerance) typically are not associated with anaphylaxis or other immediately life-threatening conditions.”²⁰⁹

²⁰³ https://www.ncbi.nlm.nih.gov/books/NBK435943/pdf/Bookshelf_NBK435943.pdf

As the Food Allergy Committee which Dr. Stallings chaired found, “The 1999 CAC [Codex Alimentarius Commission] priority list included milk, egg, fish, crustacean shellfish, peanut, soybean, tree nuts, cereal grain sources of gluten, and sulfites. Several of these items were added because the FAO [Food and Agriculture Organization of the United Nations] Technical Consultation also considered celiac disease, intolerances, and sensitivity reactions in addition to immunoglobulin E (IgE)-mediated food allergies in its deliberations. For example, gluten was included because of its association with celiac disease.” (page 284)

“In the United States, the priority list of allergenic foods was established by the Congress with the passage of the Food Allergen Labeling and Consumer Protection Act,^{6 7} [‘For an analysis on Food Allergen Labeling and Consumer Protection Act see Derr (When Food Is Poison), 2006.’] (FALCPA) of 2004. The FALCPA list mirrored the 1999 CAC list except that the FALCPA list did not address celiac disease and therefore did not recognize cereal sources of gluten as major allergenic foods.” (page 286)

²⁰⁴ https://www.ncbi.nlm.nih.gov/books/NBK435943/pdf/Bookshelf_NBK435943.pdf

²⁰⁵ <https://www.fda.gov/media/157637/download> , page 7

²⁰⁶ https://www.ncbi.nlm.nih.gov/books/NBK435943/pdf/Bookshelf_NBK435943.pdf

²⁰⁷ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4241964/pdf/nihms247178.pdf> , page 5

²⁰⁸ https://www.ncbi.nlm.nih.gov/books/NBK435943/pdf/Bookshelf_NBK435943.pdf , page 26

²⁰⁹ <https://www.fda.gov/media/157637/download>

In the FDA's Draft Guidance (page 7), the FDA relied exclusively on "Ref. 1"²¹⁰ and Ref. 2²¹¹ to define "food allergy",²¹² and that is wrong biomedically, legally, and conversationally, and as such, the definition is way too limiting. This is another example of how the Federal government has marginalized the healthcare, well-being and consumer protection needs of the Celiac community by not even believing that the evaluation of the public health importance of labeling Gluten as a Major Food Allergen is meritorious.

Below is an excerpt from Dr. Stallings letter to the FDA dated August 4, 2022 in which she opined regarding the FDA's Draft Guidance (including FDA Ref. 2 cited therein for which she served as chair and editor of) and the need to label Gluten as a Major Food Allergen:²¹³

"Our Food Allergy Committee's work for the National Academy found that 'food allergy has two key classifications: immunoglobulin E (IgE)-mediated or non-IgE-mediated' (page 4) such as Celiac Disease. However, it should be noted that while there were certain references to Celiac Disease in the Food Allergy Committee report, Celiac Disease was not covered in our report because it was 'beyond the scope of the statement of task' for the committee, not because Celiac Disease is not an essential food safety issue for the population..."

While a Non-IgE-Mediated food allergy does not trigger anaphylaxis and is not immediately life-threatening, people with Celiac Disease face potentially life-threatening and severe adverse health effects that can arise through gluten ingestion including by way of example and not limited to: anemia, cancer, heart disease, immunological scarring, intestinal damage and malnutrition...

A gluten free diet is not all that is needed to treat Celiac Disease; rather a gluten free diet is all that has ever been historically available to treat Celiac Disease. Additionally, with respect to labeling food products in the United States, the voluntary gluten free labeling scheme does not sufficiently protect consumers who are on medically required and very restrictive gluten free diets.

My strong recommendation is that gluten be labeled on all packaged foods in the United States, in accordance with the 2021 FAO/WHO Expert Consultation, just like it is in more than 85 countries around the world.²¹⁴,²¹⁵ (emphasis added)

²¹⁰ "Guidelines for the Diagnosis and Management of Food Allergy in the United States: Report of the NIAID-sponsored Expert Panel", December 2010: "The Guidelines focus on diseases that are defined as FA (see section 2.1) and include both IgE-mediated reactions to food and some non-IgE-mediated reactions to food. The Guidelines do not discuss celiac disease, which is an immunologic non-IgE-mediated reaction to certain foods. Although this is an immune-based disease involving food, existing clinical guidelines for celiac disease will not be restated here." <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4241964/pdf/nihms247178.pdf>

²¹¹ https://www.ncbi.nlm.nih.gov/books/NBK435943/pdf/Bookshelf_NBK435943.pdf

²¹² <https://www.fda.gov/media/157637/download>

²¹³ https://downloads.regulations.gov/FDA-2021-N-0553-1169/attachment_1.pdf

²¹⁴ Food Allergy Research and Resource Program at the University of Nebraska-Lincoln, <https://farrp.unl.edu/IRChart>

²¹⁵ FDA Comment ID: FDA-2021-N-0553-1169, FDA Tracking Number: 16g-mawc-nbs8, August 5, 2022, https://downloads.regulations.gov/FDA-2021-N-0553-1169/attachment_1.pdf

In other words, it is unreasonable, dangerous, and inequitable for the FDA to rely on Ref. 2 to define food allergy and food allergen to exclude Celiac Disease and Gluten from foundational definitions when Celiac Disease (a Gluten allergy) and Gluten were ‘beyond the scope of the statement of task’ for the committee which wrote Ref. 2, and not because Celiac Disease is not an essential food safety issue for the population.

G. Oats Must Be Included by the FDA as a Gluten Containing Grain and Thus Declared on All Food Packages

Oats are naturally Gluten Free. However, according to General Mills, “cross contamination [with Gluten] is inevitable.”²¹⁶ It is instructive to understand the historical and marketplace context related to the labeling of Oats as a Gluten containing grain.

In answering the question, “What is Gluten?,” the NIH’s National Library of Medicine stated that Gluten is a food protein, and that Gluten containing grains include Wheat, Barley, Rye and Oats.²¹⁷

The 1999 Codex Criteria (See FDA Ref. 25 in FDA Docket FDA-2021-N-0553) stated,

“The revised list of those foods and ingredients known to cause food allergies and intolerance and whose presence should always be declared was identified as the following: Cereals containing gluten (i.e., wheat, rye, barley, **oats**, spelt or their hybridized strains) and their products.”²¹⁸ (emphasis added)

As discussed, the 2021 FAO/WHO Expert Consultation evolved its global guidance on Gluten containing grains with respect to Oats,

“Due to the lack of data on prevalence, severity and/or potency, or due to regional consumption of some foods, the Committee recommended that some of the allergens, ... **oats, ... should not be listed as global priority allergens but [Oats] may be considered for inclusion on priority allergen lists in individual countries.**”²¹⁹ (emphasis added)

According to research cited in the FAO and WHO 2022 Risk Assessment of Food Allergens. Part 1 - Review and validation of Codex Alimentarius Priority Allergen List Through Risk Assessment. Meeting Report. Food Safety and Quality Series No. 14, Rome,

“It might be considered that oats should be on a regional priority allergen list because oats are generally contaminated, and often at significant levels, with gluten containing cereals. In Canada, taking into consideration lot-to-lot variability, approximately 88 percent of commercial oats samples (n = 133) were reported to be contaminated above the Codex-recommended gluten-free level (20 ppm), gluten concentration ranging from 21 to 3800 mg/kg of oats (Koerner et al., 2011). **If oats are not on a priority allergen list, the possible presence of (contaminated) oats as an ingredient remains, and**

²¹⁶ <https://patents.google.com/patent/US9968937B2/en>

²¹⁷ <https://pubmed.ncbi.nlm.nih.gov/28244676/>

²¹⁸ https://apps.who.int/iris/bitstream/handle/10665/42378/WHO_TRS_896.pdf ; Also see 2021 FAO/WHO Expert Consultation as detailed herein (See FDA Ref. 45 in FDA Docket FDA-2021-N-0553). Source: <http://www.fao.org/3/cb4653en/cb4653en.pdf>

²¹⁹ <http://www.fao.org/3/cb4653en/cb4653en.pdf>

several products may cause reactions in consumers with coeliac disease. For this reason, oats are included in Canadian legislation.²²⁰ (emphasis added)

On April 4, 2023, Gluten Free Watchdog published,

“In early January of 2022, Gluten Free Watchdog issued a statement warning the community about supply chain issues with oats. At Gluten Free Watchdog we have seen an increase in oats testing with quantifiable gluten either at/above 20 ppm OR above the level of gluten allowed by their certifying organization. **At this time (April, 2023), Gluten Free Watchdog cannot recommend any brand of gluten-free oats.** This includes products that are certified gluten-free or made using purity protocol oats. We will issue an update when the situation warrants.”²²¹ (emphasis added)

In addition, it is instructive to read the following from General Mills about Oats being cross contaminated with Gluten,

“Oats themselves do not contain gluten. However, oats cultivated in North America, Europe and even other parts of the world are commonly contaminated by gluten containing foreign grains, including wheat, barley, rye and triticale. This contamination is commonly known to come from various sources, mainly from the rotation of small grain crops on the same land, with residual contaminating seeds germinating with a seeded oat crop. In addition, contamination from other grains which are harvested, transported, stored and merchandized in common with oats is a contributing factor. As a result, it is not uncommon to find from 0.5% to 5.0% of these other grains mixed with commercially marketed oats. **Therefore, absent dedicating land, harvesting equipment, transporting vehicles, storage units, packaging and production facilities, and the like only for use in connection with oats, cross contamination is inevitable.**”²²² (emphasis added)

To really understand the gravitas of General Mills’s statement on the inevitability of Oats being cross contaminated with Gluten, it is important to consider the market position and expertise of General Mills in the food industry. According to General Mills’ 2021 Annual Report,

“We are a leading global manufacturer and marketer of branded consumer foods sold through retail stores. We also are a leading supplier of branded and unbranded food products to the North American foodservice and commercial baking industries. We are also a leading manufacturer and marketer in the wholesome natural pet food category. We manufacture our products in 13 countries and market them in more than 100 countries. In addition to our consolidated operations, we have 50 percent interests in two strategic joint ventures that manufacture and market food products sold in more than 120 countries worldwide.”²²³

²²⁰ <https://www.fao.org/3/cb9070en/cb9070en.pdf> , and <https://www.tandfonline.com/doi/pdf/10.1080/19440049.2011.579626?>

²²¹ <https://www.glutenfreewatchdog.org/news/gluten-free-watchdog-cannot-recommend-any-brand-of-gluten-free-oats/> and <https://www.glutenfreewatchdog.org/news/category/gluten-free-oats/>

²²² <https://patents.google.com/patent/US9968937B2/en>

²²³ https://s22.q4cdn.com/584207745/files/doc_financials/2021/ar/Final-GMI-2021-Annual-Report.pdf

H. FALCPA Has Failed Celiacs Based on a Big Lie: FALCPA Negotiations Were Scientifically Flawed from the Start with Celiac Being Incorrectly Othered as a Gluten Intolerance and Not as a Food Allergy -- No One From FDA or HHS Spoke Up and Served as an Upstander to Protect Celiacs

On August 9, 2002, Inside Washington's (Health Policy's) [FDA Week](#) reported that Senator Kennedy floated an amendment to the FALCPA memorialized,

“But the food industry source says that even though the amendment goes in the right direction, the food industry continues to oppose the bill on the grounds that a mandatory approach is not appropriate or needed, and that instead the food industry should be allowed to continue to implement its voluntary guidelines... **Critics of the bill [in the food industry] had charged that scientifically, Gluten is an intolerance not an allergen.**” (emphasis added)

On September 27, 2002, Inside Washington's (Health Policy's) FDA Week (page 5) memorialized,

“Substitute [bill] pulls mandatory Gluten declaration... This week the Senate Health Committee passed without objection a watered-down version of a bill that would require food processors to label the eight most common types of food allergens in plain English. **The substitute version, unlike the underlying bill... would not require the declaration of Gluten.**” (emphasis added)

That “science” was wrong then, and it is wrong now.

When the FALCPA was signed into law in 2004, it had already left the Celiac community behind with a voluntary labeling scheme that would not be enacted until 2014, but moreover it was incongruent with the 1999 Codex Criteria and how the international community was already starting to require the labeling of Gluten on all packaged foods. See Section V.J. in this Citizen Petition entitled, “Historical Context of Celiacs Being Underserved and Marginalized by the Federal Government.”

In addition to other research and arguments set forth in this Citizen Petition, some legal scholars believe that a strong legal argument could be made for labeling Gluten as a Major Food Allergen under an Equal Protection Clause claim whereby Celiacs have been discriminated against by the FDA. For example, the evidence suggests that FALCPA and the FDA have been using a suspect classification of Gluten as a second-class food allergen and Celiac as not a food allergy, but instead an intolerance, and therefore treating Celiac as much less serious than an IgE-Mediated food allergy. In turn, that suspect classification has then been used as a pretext to provide and perpetuate the voluntary labeling scheme of Gluten instead of a mandatory labeling scheme to declare of Gluten on all food packages in the U.S.

I. Perplexing Paradigm of Consumer Protection for 3.3 Million Celiacs: Included vs. Excluded

With the mitigation of the burden of chronic diet-related disease in mind, it is instructive to understand the following current perplexing paradigm. Unlike the FALCPA labeling scheme for the top 9 Major Food Allergens in the U.S. (Sesame as of January 1, 2023), Gluten Free labeling is permissive (voluntary) in the U.S. For example, if you are allergic to one of the top 9 Major Food Allergens, those allergens must be declared on a food label. However, if you have a Gluten

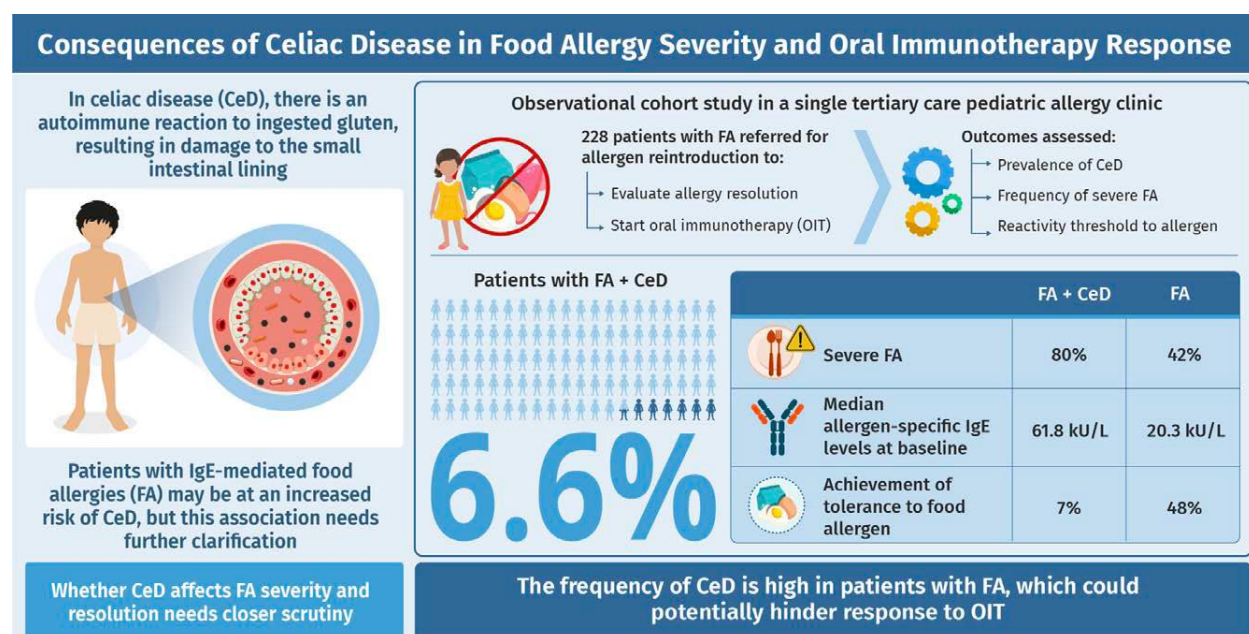
allergy, you cannot rely on the manufacturer to declare Gluten on the ingredients label. Instead, you must undertake a Gluten guessing game if the manufacturer does not voluntarily label a product gluten-free.

Priscilla Chan (from the Chan Zuckerberg Initiative) has said that “Luck is not a national strategy. We need to build strategies that take luck out of the equation for every person.”²²⁴ However, absent required labeling and any rescue medication, every time that Jax and 3.3 million Celiacs eat, there is luck involved that they do not get violently sick.

Wheat is required to be labeled in the U.S., but Barley, Rye and Oats (collectively the other sources of Gluten with most Oats having had cross contact with Gluten Containing Grains) are not required to be labeled in the U.S. Imagine if for those with a Tree Nut allergy only Almonds were required to be labeled, but not other Tree Nuts such as Pecans and Walnuts, for example. That would create a massive food safety issue and gap that needed to be closed. Fortunately for those with a Tree Nut allergy that scenario is not the case. But that similar massive safety issue and gap does exist with voluntary Gluten labeling for 3.3 million American Celiacs.

J. Celiac Disease Frequency Is Increased in IgE-Mediated Food Allergy and Could Affect Allergy Severity and Resolution

According to the Journal of Pediatric Gastroenterology and Nutrition in January 2023, Celiac Disease frequency (Non-IgE-Mediated) is increased in patients with an IgE-Mediated food allergy and could affect allergy severity and resolution.²²⁵



Celiac Disease Frequency is Increased in IgE-mediated Food Allergy and Could Affect Allergy Severity and Resolution
Lega et al. (2022)

JPGN
Journal of Pediatric Gastroenterology and Nutrition

²²⁴ <https://chanzuckerberg.com/about/our-approach/>

²²⁵ Lega S, Badina L, De Leo L, Andrade S, Ziberna F, Gaita B, Di Leo G, Bramuzzo M, Barbi E, Not T, Berti I. Celiac Disease Frequency Is Increased in IgE-Mediated Food Allergy and Could Affect Allergy Severity and Resolution. Journal of Pediatric Gastroenterol Nutrition. 2023 January 1;76(1):43-48. doi: 10.1097/MPG.0000000000003629. Epub 2022 Sep 29. PMID: 36574002. <https://pubmed.ncbi.nlm.nih.gov/36574002/>

V. President Biden’s Executive Order 13985 On Advancing Racial Equity and Support for Underserved Communities Through the Federal Government & President Biden’s Executive Order 14091: Further Advancing Racial Equity and Support for Underserved Communities Through the Federal Government

“Why should there be hunger and deprivation in any land, in any city, at any table, when man has the resources and the scientific know-how to provide all mankind with the basic necessities of life? There is no deficit in human resources. The deficit is in human will.”

--Dr. Martin Luther King Jr.

“The heart of the question is whether all Americans are to be afforded equal rights and equal opportunities, whether we are going to treat our fellow Americans as we want to be treated. If an American, because his skin is dark, cannot eat lunch in a restaurant open to the public, if he cannot send his children to the best public school available, if he cannot vote for the public officials who will represent him, if, in short, he cannot enjoy the full and free life which all of us want, then who among us would be content to have the color of his skin changed and stand in his place? Who among us would then be content with the counsels of patience and delay?”

-- President John F. Kennedy

A. Embedding Fairness in Decision-Making Processes

It is instructive to view this Citizen Petition as well as all comments received on the FDA’s Draft Guidance²²⁶ about labeling Gluten through the lens of President Biden’s “Executive Order 13985 On Advancing Racial Equity and Support for Underserved Communities Through the Federal Government”, dated January 20, 2021 and President Biden’s “Executive Order 14091: Further Advancing Racial Equity and Support for Underserved Communities Through the Federal Government”, dated February 16, 2023:²²⁷

“It is therefore the policy of my Administration that the Federal Government should pursue a comprehensive approach to advancing equity for all, including people of color and others who have been historically underserved, marginalized, and adversely affected by persistent poverty and inequality. Affirmatively advancing equity, civil rights, racial justice, and equal opportunity is the responsibility of the whole of our Government. Because advancing equity requires a systematic approach to embedding fairness in decision-making processes, executive departments and agencies (agencies) must recognize and work to redress inequities in their policies and programs that serve as barriers to equal opportunity. By advancing equity across the Federal Government, we can create opportunities for the improvement of communities that have been historically underserved, which benefits everyone.”²²⁸

²²⁶ <https://www.regulations.gov/docket/FDA-2021-N-0553/comments?filter=celiac>

²²⁷ <https://www.federalregister.gov/documents/2023/02/22/2023-03779/further-advancing-racial-equity-and-support-for-underserved-communities-through-the-federal>

²²⁸ <https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government/>

B. Equity Definition: Section 2(a) of Executive Orders 13985 & 14091

Equity Definition: Section 2(a) of Executive Orders 13985 & 14091 provides that,

“The term ‘equity’ means the consistent and systematic fair, just, and impartial treatment of all individuals, including individuals who belong to underserved communities that have been denied such treatment, such as Black, Latino, and Indigenous and Native American persons, Asian Americans and Pacific Islanders and other persons of color; members of religious minorities; lesbian, gay, bisexual, transgender, and queer (LGBTQ+) persons; persons with disabilities; persons who live in rural areas; and persons otherwise adversely affected by persistent poverty or inequality.” Further, section 2(b) provides that, “the term ‘underserved communities’ refers to populations sharing a particular characteristic, as well as geographic communities, that have been systematically denied a full opportunity to participate in aspects of economic, social, and civic life, as exemplified by the list in the preceding definition of equity.”²²⁹ (emphasis added)

C. The Celiac Community Represents an Underserved Community Which Shares a Particular Characteristic including a Chronic Disability

The Celiac community represents an underserved community which shares a particular characteristic including a chronic disability as per the Fourth Circuit Court of Appeals²³⁰ and a potentially life-threatening and life-debilitating food allergy to eating Gluten with numerous adverse health consequences, etc. associated with the ingestion of Gluten. The Celiac community has been systemically denied a full opportunity to participate in aspects of economic, social and civil life as detailed below. See Section V.I. in this Citizen Petition entitled, “Example of How Celiacs Have Been Denied Opportunity to Participate Fully in Economic, Social & Civic Life.”

D. Celiac Impacts Several Major Life Activities

For someone with Celiac Disease, eating, sleeping, thinking, concentrating, learning and working are major life activities²³¹ that can be impacted on a daily basis, and there are various bodily systems which can be impacted including: gastrointestinal (digestive), nervous (anxiety, ataxia and neuropathy), skeletal, reproductive (infertility) and integumentary. As per the Biden-Harris Administration National Strategy on Hunger, Nutrition, and Health as part of the White

²²⁹ <https://www.federalregister.gov/documents/2021/01/25/2021-01753/advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government>

²³⁰ In May 2019, in a case involving the disability rights of a child who has a severe allergy to Gluten, the U.S. Fourth Circuit Court of Appeals cited that “[t]he ADA [Americans with Disabilities Act] defines a ‘disability’ in pertinent part as ‘a physical or mental impairment that substantially limits one or more major life activities’” and that “[e]ating is a major life activity.” J.D., by his father and next friend, Brian Doherty, Plaintiff-Appellant v. Colonial Williamsburg Foundation, Defendant-Appellee, National Disability Rights Network; Disability Law Center for Virginia; Scott Hayes; Virginia Food Allergy Advocates, Amici Supporting Appellant. Vacated and Remanded -Appeal from the United States District Court for the Eastern District of Virginia, at Newport News. Rebecca Beach Smith, District Judge. (4:17-cv-00101-RBS-RJK); United States Court of Appeals for the Fourth Circuit, No. 18-1725, Argued: January 29, 2019; Decided: May 31, 2019, See www.celiacjourney.com/williamsburg and https://e283a7ed-372c-4d14-b65c-6fe40bfad779.usrfiles.com/ugd/e283a7_82b2da0c6e2d40ee9f55e3e57ef820a4.pdf

²³¹ <https://www.dol.gov/agencies/ofccp/faqs/americans-with-disabilities-act-amendments#Q5>

House Conference on Hunger, Nutrition, and Health, “diet-related diseases are some of the leading causes of death and disability in the U.S.”²³²

According to the Biden-Harris Administration, there is more work to do to live up to the promise of the ADA and one of those areas arguably is providing consumer protection to Celiacs by labeling Gluten. “Grounded in four core outcomes of full participation, equal opportunity, independent living, and economic self-sufficiency, the ADA prohibits discrimination on the basis of disability in public accommodations, employment, transportation, and community living and provides recourse for people with disabilities who faced discrimination. The nation has made significant progress since the law was signed, **but there is more work to do to live up to the promise of the ADA.**”²³³

E. Racial Disparities in Awareness, Diagnosis and Treatment of Celiac Disease for Black Americans and Other Minorities

According to Beyond Celiac, “in a study by the University of Chicago and Harvard School of Public Health, researchers found that Black Americans who have symptoms associated with Celiac Disease have 90% decreased odds of receiving the appropriate follow-up for diagnosis.”²³⁴ Additional findings from Beyond Celiac include:

- “Black Americans (63%) are significantly more likely than Hispanic Americans (49%) and White Americans (47%) to have no awareness of celiac disease and/or gluten-sensitivity, suggesting potential health inequities in both diagnosis and treatment, according to a nationwide benchmark survey conducted by The Harris Poll on behalf of Beyond Celiac, the leading catalyst for a celiac disease cure.”²³⁵
- “Black, Hispanic, and Latino patients and those with public insurance presenting with celiac disease symptoms are less likely to receive appropriate follow-up compared to white patients and those with private insurance.”²³⁶

F. Examples of How Celiacs Have Been Historically Underserved and Marginalized by the Federal Government

It is further instructive to understand how the Celiac community has been historically underserved and marginalized by our Federal government, including by way of example and not limitation:

- **NIH Research** - Underfunding NIH biomedical research for Celiac Disease over many years (on average, the Federal government spent about \$3.4 million annually on Celiac research from 2011-2020, which is about \$1.00 per American with Celiac per year, and that is way too low). Funding for Celiac research has been disproportionately low as compared with research funding for food allergies, digestive diseases, auto-immune diseases and/or foodborne illness, and in consideration of these factors: disease prevalence, treatment burden and other

²³² <https://www.whitehouse.gov/wp-content/uploads/2022/09/White-House-National-Strategy-on-Hunger-Nutrition-and-Health-FINAL.pdf>

²³³ <https://www.whitehouse.gov/briefing-room/statements-releases/2022/07/26/fact-sheet-the-biden-%E2%81%A0harris-administration-marks-the-anniversary-of-the-americans-with-disabilities-act/>

²³⁴ <https://www.prnewswire.com/news-releases/beyond-celiac-identifies-health-disparities-in-celiac-disease-awareness-diagnosis-and-treatment-for-black-americans-301610858.html>

²³⁵ <https://www.prnewswire.com/news-releases/beyond-celiac-identifies-health-disparities-in-celiac-disease-awareness-diagnosis-and-treatment-for-black-americans-301610858.html>

²³⁶ <https://www.beyondceliac.org/celiac-news/beyondceliac-takeda-healthcare-equity-initiative/>

available treatment options.²³⁷ According to a Congressionally mandated report “Enhancing NIH Research on Autoimmune Disease” published in May 2022 from the National Academy of Sciences, Engineering and Medicine, “There is a lack of long-term (20 years or more) population-based epidemiology studies on autoimmune disease, the committee found. Such studies would allow for, among other things, assessing trends, risk factors, and costs of disease; identifying differences among population subgroups; and **determining the prevalence of under-researched autoimmune diseases, such as celiac disease.**”²³⁸ (emphasis added)

- **Voluntary Gluten Labeling Scheme & Identification of Sources of Gluten** - Labeling Gluten only with a voluntary scheme since 2014. Under FALCPA, mandatory labeling of the top 8 Major Food Allergens started on January 1, 2006. In contrast, the FDA delayed action on the FDA’s final rule for Gluten Free labeling until August 5, 2014. This unnecessary delay happened notwithstanding the House of Representatives Report on FALCPA stating, “Given the devastating nature of celiac disease, the Committee urges the Secretary to move expeditiously in implementing the requirements of this section.”²³⁹ The FDA’s six year delay also happened in spite of a FALCPA imposed deadline for Gluten Free labeling of August 2, 2008,²⁴⁰ and that on January 23, 2007, the FDA published its proposed rule on the voluntary labeling of Gluten Free products that for all intents was the final rule which was ultimately enacted on August 5, 2014.²⁴¹ See Section X. in this Citizen Petition, “What’s Past Suggests Prologue and That’s Why We Need Help from President Biden, Secretary Becerra, Commissioner Califf, Deputy Commissioner Jones and the HHS Equity Team.” Further, the FDA does not even acknowledge that Oats can be a common source of Gluten through cross contamination with Wheat, Barley and Rye.²⁴² See Section IV.G. in this Citizen Petition entitled, “Oats Must Be Included by the FDA as a Gluten Containing Grain and Thus Declared on All Food Packages.”
- **Military Service** - Disqualifying Celiacs from service in the military.²⁴³ Historically, it is instructive to reflect that there were other relatively recent exclusionary practices in the U.S. Military which were embodied in the Don’t Ask, Don’t Tell “set of policies, laws, and regulations governing how the U.S. Military dealt with gay, lesbian, and bisexual service members... In 2011, the ‘Don’t Ask, Don’t Tell’ policy was formally repealed by the Obama Administration under Pub. L. 111-321.”²⁴⁴

²³⁷ <http://www.celiacjourney.com/briefing>

²³⁸ <https://www.nationalacademies.org/news/2022/05/nih-should-create-an-office-of-autoimmune-disease-research-says-new-report>

²³⁹ H.R. Rep. No. 108-608, at 18. (2004), <https://www.congress.gov/108/crpt/hrpt608/CRPT-108hrpt608.pdf>

²⁴⁰ https://downloads.regulations.gov/FDA-2021-N-0553-1584/attachment_1.pdf, pages 79-96; <https://www.federalregister.gov/documents/2013/08/05/2013-18813/food-labeling-gluten-free-labeling-of-foods>

²⁴¹ <https://www.govinfo.gov/content/pkg/FR-2007-01-23/pdf/FR-2007-01-23.pdf>

²⁴² <https://www.fda.gov/consumers/consumer-updates/gluten-free-means-what-it-says>

²⁴³ U.S. Department of Defense, DoD Instruction 6130.03, Medical Standards for Appointment, Enlistment, or Induction into the Military Services, Section 5.12.c.(3), May 6, 2018, <https://www.esd.whs.mil/DD/>

²⁴⁴ https://www.law.cornell.edu/wex/don%27t_ask_don%27t_tell

We suggest that FALCPA's voluntary Gluten Free labeling scheme is as convoluted and ill-conceived as Don't Ask, Don't Tell.

On February 16, 2016, Senator Ted Cruz (who was then a Republican presidential candidate) even went so far as to pledge that if elected, he would not to provide gluten-free military meals – “That’s why the last thing any commander should need to worry about is the grades he is getting from some plush-bottomed Pentagon bureaucrat for political correctness or social experiments -- or providing gluten-free MREs [Meal, Ready to Eat].”²⁴⁵

In addition to it being time for the Federal government to allow Celiacs to serve in the U.S. Military by accommodating their medically required Gluten Free diet, it is also time for the FDA to require that Gluten be labeled on all packaged foods to protect more than 3.3 million Americans with Celiac who have a potentially life-threatening and life-debilitating food allergy to Gluten.

- **CDC’s Index of Diseases** - Excluding Celiac Disease from the CDC’s Index of Diseases & Conditions²⁴⁶
- **Medicare** - Excluding Celiacs from Medicare coverage for medical nutrition therapy (MNT) which is currently limited to patients with diabetes and kidney failure, leaving millions of older Americans with leading diet-related diseases, without access to nutrition counseling.²⁴⁷
- **FDA Research** - Excluding Celiac Disease from “beyond the scope of the statement of task” from the Federally funded²⁴⁸ National Academies of Sciences, Engineering, and Medicine, Committee on Food Allergies which published the seminal work: “Finding a Path to Safety in Food Allergy: Assessment of the Global Burden, Causes, Prevention, Management and Public Policy.”²⁴⁹

²⁴⁵ <https://time.com/4225884/ted-cruz-military-gluten-free-meals/>

²⁴⁶ <https://www.cdc.gov/health-topics.html#f> , and <https://www.cdc.gov/health-topics.html#cdc-atozlist>

²⁴⁷

https://www.dropbox.com/s/2qxc03pc1i5xg49/Tufts_WhiteHouseReport_R16_IP22_082122.pdf?dl=0

²⁴⁸ Finding a Path “was supported by federal sponsors: the Food and Drug Administration (Contract No. HHSP233201400020B/HHSP23337025), the Food and Nutrition Service of the U.S. Department of Agriculture (Grant # FS_NAS_IOM_FY2015_01), and the National Institute of Allergy and Infectious Diseases. Source: Page ii,

https://www.ncbi.nlm.nih.gov/books/NBK435943/pdf/Bookshelf_NBK435943.pdf

²⁴⁹ https://www.ncbi.nlm.nih.gov/books/NBK435943/pdf/Bookshelf_NBK435943.pdf

As the Food Allergy Committee which Dr. Stallings chaired found,

“The 1999 CAC [Codex Alimentarius Commission] priority list included milk, egg, fish, crustacean shellfish, peanut, soybean, tree nuts, cereal grain sources of gluten, and sulfites. Several of these items were added because the FAO [Food and Agriculture Organization of the United Nations] Technical Consultation also considered celiac disease, intolerances, and sensitivity reactions in addition to immunoglobulin E (IgE)-mediated food allergies in its deliberations. For example, gluten was included because of its association with celiac disease.” (Page 284)

“In the United States, the priority list of allergenic foods was established by the Congress with the passage of the Food Allergen Labeling and Consumer Protection Act, 67 [“For an analysis on

According to Dr. Virginia Stallings, the Editor and Chair of Finding a Path, “Our Food Allergy Committee’s work for the National Academy found that “food allergy has two key classifications: immunoglobulin E (IgE)-mediated or non-IgE-mediated” (page 4) such as Celiac Disease. However, it should be noted that while there were certain references to Celiac Disease in the Food Allergy Committee report, Celiac Disease was not covered in our report because it was ‘beyond the scope of the statement of task’ for the committee, not because Celiac Disease is not an essential food safety issue for the population.”²⁵⁰ In other words, the Federal government paid for this seminal report which excluded Celiac from the statement of task, and then the FDA relied upon Finding a Path to exclude Gluten from evaluating the public health importance of food allergen other than the Major Food Allergens.²⁵¹

- **FDA’s 2022 Food Code** - Excluding Celiac Disease and Gluten from the FDA’s 2022 Food Code.²⁵² According to the 2022 Recommendations of the United States Public Health Service and Food and Drug Administration, “The Food Code is a model for safeguarding public health and ensuring food is unadulterated and honestly presented when offered to the consumer. It represents FDA’s best advice for a uniform system of provisions that address the safety and protection of food offered at retail and in food service.”²⁵³ The 2022 Food Code is 668 pages, and includes sections on “Food Labels and Other Forms of Information,”²⁵⁴ “List of Ingredients,”²⁵⁵ “Food Allergen Labeling”²⁵⁶ and “Food Allergens

Food Allergen Labeling and Consumer Protection Act see Derr (When Food Is Poison), 2006.’] (FALCPA) of 2004. The FALCPA list mirrored the 1999 CAC list except that the FALCPA list did not address celiac disease and therefore did not recognize cereal sources of gluten as major allergenic foods.” (Page 286)

²⁵⁰ https://downloads.regulations.gov/FDA-2021-N-0553-1169/attachment_1.pdf

²⁵¹ https://downloads.regulations.gov/FDA-2021-N-0553-1584/attachment_1.pdf

²⁵² “This model is offered for adoption by local, state, and federal governmental jurisdictions for administration by the various departments, agencies, bureaus, divisions, and other units within each jurisdiction that have been delegated compliance responsibilities for food service, retail food stores, or food vending operations. Alternatives that offer an equivalent level of public health protection to ensure that food at retail and foodservice is safe are recognized in this model.” Source: 2022 Food Code, January 18, 2023 Version,

<https://www.fda.gov/media/164194/download>

²⁵³ 2022 Food Code, January 18, 2023 Version, <https://www.fda.gov/media/164194/download>

²⁵⁴ “Food labels serve as a primary means by which consumers can make informed decisions about their food selections... Unintended food allergen food allergen exposures poses a serious risk to consumers with food allergies. Consumers with food allergies depend on allergen information that is made available either verbally or written by the food establishment. To address consumer notification of major food allergens in unpackaged foods served or sold within food establishments, the Conference for Food Protection, Issue 2020-II-015, recommended that a new provision be added.” 3-602.12, Annex 3-144, <https://www.fda.gov/media/164194/download>

²⁵⁵ “A list of ingredients on the label enables a consumer to make an informed decision about a packaged food product. Therefore it is important that the list of ingredients accurately describe all of the ingredients present in the food.” 3-602.12, Annex 3-144, <https://www.fda.gov/media/164194/download>

²⁵⁶ Annex 3-145, <https://www.fda.gov/media/164194/download>

As Food Safety Hazards.”²⁵⁷ However, the FDA’s 2022 Food Code did not mention Celiac Disease at all, and it only mentioned Gluten in two passing references including in a Web site address²⁵⁸ and an historical reference to FALCPA.²⁵⁹ According to the 2002 Senate Report on FALCPA,

“The [FALCPA] legislation directs the Secretary to pursue revision of the Food Code to provide guidelines for preparing allergen-free foods in food establishments. It also directs the Secretary to provide technical assistance relating to emergency treatment of allergic responses to foods.”

²⁵⁷ “Recent studies indicate that over 11 million Americans suffer from one or more food allergies. A food allergy is caused by a naturally-occurring protein in a food or a food ingredient, which is referred to as an allergen. For unknown reasons, certain individuals produce immunoglobulin E (IgE) antibodies specifically directed to food allergens. When these sensitive individuals ingest sufficient concentrations of foods containing these allergens, the allergenic proteins interact with IgE antibodies and elicit an abnormal immune response. A food allergic response is commonly characterized by hives or other itchy rashes, nausea, abdominal pain, vomiting and/or diarrhea, wheezing, shortness of breath, and swelling of various parts of the body. In severe cases, anaphylactic shock and death may result.

Many foods, with or without identifiable allergens, have been reported to cause food allergies. However, FDA believes there is scientific consensus that the following foods can cause a serious allergic reaction in sensitive individuals; these foods account for 90% or more of all food allergies: Milk, Egg, Fish (such as bass, flounder, or cod), Crustacean shellfish (such as crab, lobster, or shrimp), Tree nuts (such as almonds, pecans, or walnuts), Wheat, Peanuts, Soybeans, and Sesame.

Consumers with food allergies rely heavily on information contained on food labels to avoid food allergens. Each year, FDA receives reports from consumers who have experienced an adverse reaction following exposure to a food allergen. Frequently, these reactions occur either because product labeling does not inform the consumer of the presence of the allergenic ingredient in the food or because of the cross-contact of a food with an allergenic substance not intended as an ingredient of the food during processing and preparation.” Annex 4-11, <https://www.fda.gov/media/164194/download>

²⁵⁸ Annex 2-10: Food Allergen Labeling and Consumer Protection Act of 2004. Public Law 108-282 <https://www.fda.gov/food/food-allergensgluten-free-guidance-documents-regulatory-information/food-allergen-labeling-and-consumer-protection-act-2004-falcpa>

²⁵⁹ Annex 4-12: “Within 2 years of the date of enactment of the new law (i.e., by August 2, 2006), FDA must issue a proposed rule, and within 4 years of the date of enactment of the new law (i.e., by August 2, 2008), FDA must issue a final rule to define and permit the use of the term “gluten-free” on food labeling.” For the record, the FDA Food Code does not acknowledge that on January 23, 2007, the FDA published its proposed rule on the voluntary labeling of Gluten Free products (<https://www.govinfo.gov/content/pkg/FR-2007-01-23/pdf/FR-2007-01-23.pdf>) that for all intents was the final rule ultimately enacted on August 5, 2014, and that the U.S. lagged way behind our peer countries which had all set labeling standards for Gluten Free foods and followed the 1999 Codex Criteria to label Gluten as a Priority/Major Food Allergen. Notwithstanding the statutory requirement to implement a final rule by August 2, 2008, the FDA was delayed in doing so by more than 6 years, all the while the Celiac community was left in limbo.

“Numerous food establishments, including restaurants, grocery store delicatessens and bakeries, and school cafeterias are working to better serve those consumers with food allergies. Private guidelines demonstrating and recommending ways to prepare allergen-free foods have helped to educate such food establishments. Revision of the Food Code to include similar recommendations, however, will help to better alert the food establishments to the problem food allergies pose to public health and make the distribution of such information more widespread.”²⁶⁰

The 2022 Food Code also misleadingly stated that the “FDA believes there is scientific consensus that the following foods can cause a serious allergic reaction in sensitive individuals; these foods account for 90% or more of all food allergies.”²⁶¹ This 90% statistic is misleading in that it only includes IgE-Mediated food allergies and excludes Celiac Disease (see Section VI. in this Citizen Petition entitled “Question: Are 90% of Food-Sensitive Americans Helped by the Food Allergen Labeling and Consumer Protection Law? Answer: NO!”).

- **NIH’s Research, Condition, and Disease Categories List** - Excluding Celiac Disease (through June 2022) from the NIH’s “Estimates of Funding for Various Research, Condition, and Disease Categories (RCDC)”²⁶² that provides research and funding data on how NIH allocates its financial resources. Celiac was finally added to the RCDC list in July 2022 following the House Appropriations Committee distributing its FY2023 budget report which included the following language about Celiac Disease: “The Committee thanks NIH for establishing a Research Condition, Disease Categorization (RCDC) for celiac disease.”²⁶³
- **DoD** - Excluding Celiac Disease research funding (from 1992 through December 2022) from the U.S. Department of Defense Congressionally Directed Medical Research Program (DoD-CDMRP)²⁶⁴ Peer Review Medical Research Listing. The DoD-CDMRP describes its Peer Review Medical Research Program (“PRMRP”) this way: “Each year, the PRMRP solicits research applications under topic areas directed by Congress, which address a wide range of fields of study. The PRMRP is committed to supporting research that has the potential to profoundly impact the development and implementation of medical devices, drugs, and clinical guidance that will enhance the precision and efficacy of prevention, diagnosis, and treatment across a wide range of disciplines including autoimmune diseases and immunology...”²⁶⁵ According to the U.S. Army Medical Research and Development Command, autoimmune “disorders impact U.S. Service Members, Veterans, and their beneficiaries and can produce a range of debilitating symptoms that interfere with an individual’s daily duties and require long-term care, incurring significant costs for the Military Health System. As a result, autoimmune disorders pose a risk to the effectiveness and readiness of the military force. The PRMRP Autoimmune Diseases and Immunology portfolio supports research into the underlying mechanisms and treatment identification for these disorders with the goal of reducing morbidity. During FY16-FY20, the PRMRP funded

²⁶⁰ <https://www.congress.gov/107/crpt/srpt322/CRPT-107srpt322.pdf>

²⁶¹ Annex 3-145, <https://www.fda.gov/media/164194/download>

²⁶² <https://report.nih.gov/funding/categorical-spending#/>

²⁶³ <https://www.govinfo.gov/content/pkg/CRPT-117hrpt403/html/CRPT-117hrpt403.htm>

²⁶⁴

<https://crsreports.congress.gov/product/pdf/IF/IF10349?eType=EmailBlastContent&eId=f11b707e-ca9a-4b10-b6df-afea47b3cb2e>

²⁶⁵ <https://cdmrp.health.mil/prmrp/pbks/prmrppbk2022.pdf>

44 awards related to autoimmune disorders and food allergies totaling \$59.9M.”²⁶⁶ In other words, from 1992-2022, the PRMRP never studied Celiac Disease (including from 2016-2020 when almost \$60 million was spent on “Autoimmune Diseases and Immunology” including on food allergies).²⁶⁷ Advocacy by Celiac Journey along with other Celiac Disease advocacy organizations and the Defense Research Health Consortium (“DHRC”) finally turned the tide with the PRMRP starting in 2023 so that access to funding for Celiac research will be made available through the DoD-CDMRP’s Peer Review Medical Research Listing.²⁶⁸

- **NIAID Autoimmune Diseases Coordinating Committee** - Excluding representation from Celiac Disease advocacy organization(s) on the National Institute of Allergy and Infectious Diseases (“NIAID”) Autoimmune Diseases Coordinating Committee (“ADCC”) from 1998-2020.²⁶⁹ As of May 29, 2020, there were 35 members from the Federal government (primarily from the NIH, but also the FDA), as well as 17 members from patient advocacy organizations represented on the ADCC. “NIAID chairs the NIH Autoimmune Diseases Coordinating Committee (ADCC), which was established in 1998 at the request of Congress. The purpose of the ADCC is to facilitate coordination of research across the National Institutes of Health (NIH), federal agencies, professional societies, and patient and advocacy organizations with an interest in autoimmune diseases.”²⁷⁰ It was not until after the “Celiac Disease-Focused Autoimmune Disease Coordinating Committee Meeting” on May 29, 2020²⁷¹ that the Celiac Disease Foundation and Beyond Celiac were invited to join the ADCC.²⁷²

On May 29, 2020, NIAID’s “Celiac Disease-Focused Autoimmune Disease Coordinating Committee Meeting” was held and Marilyn Geller, CEO of the Celiac Disease Foundation presented. After Ms. Geller completed her remarks, Dr. Annette Rothermel, Section Chief, Autoimmune and Primary Immunodeficiency Diseases Section, Division of Allergy Immunology and Transplantation at the NIH said, “I’m just going to ask the question because I think maybe for this audience, it might be surprising to them that the Gluten Free diet is not the be all and end all, it’s not, it really doesn’t limit; I mean it [Gluten Free diet] isn’t

²⁶⁶ <https://cdmrp.health.mil/prmrp/pbks/prmrppbk2022.pdf>

²⁶⁷ <https://cdmrp.health.mil/prmrp/pbks/prmrppbk2022.pdf>

²⁶⁸ <https://celiac.org/about-the-foundation/featured-news/2023/01/marilynsmessagejanuary2023/>

²⁶⁹ As of July 1, 2020, of the 52 members of the ADCC, there were 17 members representing specific diseases. A full one third of the ADCC members came from patient advocacy organizations outside of the NIH. There were no representatives of any organization or physician/scientist representing the Celiac Disease community. However, there were multiple non-NIH employees on the ADCC including representatives for the following: Crohn’s/Colitis (3 people); Type 1 Diabetes (2 people), Juvenile Diabetes (1 person); Sjogren’s Syndrome (2 people), Lupus (1 person), Arthritis (1 person); Multiple Sclerosis (1 person), Psoriasis (1 person), Neuromyelitis Optica (NMOSD)/Devic disease (1 person).

Source:

<https://web.archive.org/web/20200713010533/https://www.niaid.nih.gov/about/autoimmune-diseases-coordinating-committee>

²⁷⁰ <https://www.niaid.nih.gov/about/autoimmune-diseases-committee>

²⁷¹ <https://www.niaid.nih.gov/sites/default/files/2020-ADCC-Agenda.pdf>

²⁷² <https://www.niaid.nih.gov/about/autoimmune-diseases-coordinating-committee-members>

working as well as I think most of us thought it would.”²⁷³ This was a shocking admission that suggests the pernicious impact that the lack of Federal research funding for Celiac has had with regard to how the NIH has been prioritizing its research focus and allocation of funding based on treatment burden, treatment options and disease prevalence. In other words, Dr. Rothermel’s comments suggest that the Gluten Free diet is all that is needed to treat Celiac Disease, as opposed to all that has ever been historically available. Dr. Rothermel’s candid comment also suggests how this pernicious impact has extended to other government agencies such as the FDA when it comes to implementing consumer protection with voluntary labeling of Gluten.²⁷⁴

- **National Strategy on Hunger, Nutrition and Health** - Excluding Celiac Disease, Gluten and Food Allergies from the Biden-Harris Administration National Strategy on Hunger, Nutrition, and Health as part of the White House Conference on Hunger, Nutrition, and Health.^{275 276}

²⁷³

<https://www.dropbox.com/s/lb8ztfpyw1or2q1/ADCC%2005292020%20Zoom%20Meeting%20Recording%205-29-20.mp4?dl=0> ; 32:10-33:57 mark

²⁷⁴ In a follow up email from Dr. Rothermel to Jon Bari, Dr. Rothermel clarified her comments by stating, “As to your question about who commented that it might be surprising that the GFD is not working so well for many celiac patients, I did make a comment to the effect that the audience [NIAID’s Auto-immune Disease Coordinating Committee] might have found it surprising that the gluten free diet is not a cure and really isn’t working as many think it does. I made this comment to emphasize the point for meeting participants not expert in celiac disease, as I thought many would find this surprising. My intent was to hit home that the gluten free diet is not a cure as many may think.” July 20, 2020.

²⁷⁵ <https://www.whitehouse.gov/wp-content/uploads/2022/09/White-House-National-Strategy-on-Hunger-Nutrition-and-Health-FINAL.pdf>

²⁷⁶ While the authors of this Citizen Petition to Secretary Becerra and Commissioner Califf recognize that the National Strategy is a framework, many in the food allergy community, including the authors of this Citizen Petition, had provided details comments to help inform the National Strategy, and were thus very disappointed that there was no express reference to “food allergies” including Celiac Disease, in the National Strategy. We were also disappointed in the placement of food labels was only in Pillar 3 in the context of making “healthy choices.” We felt food labeling and particularly improved allergen labeling belonged in Pillar 2: “Integrate nutrition and health: Prioritize the role of nutrition and food security in overall health, including disease prevention and management, and ensure that our health care system addresses the nutrition needs of all people.”

For example, there was only one reference in the National Strategy to food allergens (i.e., “ingredient, and allergen information”), and this was in the context of online sales, “Facilitate making nutrition information easily available when grocery shopping online. While consumers increasingly use e-commerce to shop for groceries, nutrition information is not uniformly presented or always made easily accessible. HHS FDA will publish a request for information to gather public input regarding industry practices, technology, and current challenges to inform guidance for the food industry on nutrition, ingredient, and allergen information that should be available for groceries sold online.” (National Strategy, page 22)

This suggests at least two biases against Celiacs:

- **USDA’s Dietary Guidelines** - Excluding Celiac Disease from the USDA’s 164 page “Dietary Guidelines for Americans 2020 - 2025, Make Every Bite Count with the Dietary

A) The list of Major Food Allergens currently required to be labeled is finite (already established) and adequately informs and safeguards the public about potentially life-threatening food allergens on the product labels themselves, notwithstanding the FDA asking for public comments in April 2022 on evaluating the public health importance of food allergens other than the Major Food Allergens (FDA Docket FDA-2021-N-0553). In total, there were 1,907 comments submitted to the FDA, and 1,576 comments mentioned Celiac and/or Gluten as a food allergen (82.6%).

B) This goal in the National Strategy is a retailing/IT issue in terms of digital merchandising of content (i.e., label contents for nutritional and allergen information), as opposed to a food manufacturer issue.

Putting labeling in just Pillar 3 of the National Strategy, and the manner in which it was done, suggests that this is more about nutrition than ingredients including allergens, and as such, it appears to be more about a “nice to have” or “should have” as opposed to a “must have.”

Nutrition is fundamental for everyone, and it is important to understand nutritional elements (i.e., sodium, trans fat, sugar, etc.). However, for those with food allergies, the concept of making healthy choices is secondary to making safe choices that are free of the said allergen to which their immune system mounts a potentially life-threatening and life-debilitating response. In other words, before even worrying about the nutritional value, those with food allergies must cross a safety threshold as to safe ingredients. Just because some food may be healthy for some, that does not mean that these are safe choices for the those with food allergies.

As U.S. Senator Royal S. Copeland, MD (D, NY, 1923-1938) said, “What is food for one is poison for another.” (Source: “Hearing Before the Senate Comm. on Commerce, 73d Cong. (1934), reprinted in Charles Wesley Dunn, Federal Food, Drug, and Cosmetic Act: A Statement of Its Legislative Record 1176 (1987).], at 1176.”

<https://biddle.on.worldcat.org/search/detail/577790092?queryString=no%3A577790092>)

For example, while a Non-IgE-Mediated food allergy does not trigger anaphylaxis and is not immediately life-threatening, people with Celiac Disease face potentially life-threatening and severe adverse health effects that can arise through Gluten ingestion including by way of example: anemia, cancer, heart disease, immunological scarring, intestinal damage and malnutrition. Personally, my son Jax had severe intestinal damage at age 5 from eating Gluten for some extended period of time (we just do not know how long he had Celiac for prior to be diagnosed) which caused malnutrition and anemia. The ingestion of Gluten also caused to failure to thrive, and his intestine took years to heal (although he is still anemic), but every time he accidentally gets Glutened (like he was on April 1, 2023 as illustrated on the cover of this Citizen Petition), he gets violently ill (like food poisoning) and the auto-immune response repeats to attack his small intestine.

Adding labeling of Gluten to the National Strategy in Pillar #2 makes more sense for those with a Celiac Disease, “Integrate nutrition and health: Prioritize the role of nutrition and food security in overall health, including disease prevention and management, and ensure that our health care system addresses the nutrition needs of all people.”

Guidelines”²⁷⁷ In spite of discussion over other food allergens, there was not one mention Celiac Disease or Gluten.

- **HHS Secretary Alexander Azar Has Celiac Disease, But Did Not Do Enough to Meaningfully Improve the Lives of Those with Celiac** – In spite of former HHS Secretary Alexander Azar having Celiac Disease himself, Secretary Azar referred to Celiac as an “incurable, hereditary disorder that millions of Americans, including myself, live with.”²⁷⁸ Secretary Azar’s tenure represented a once in a generation opportunity to meaningfully move the ball down the field with biomedical research to find treatment(s) other than a strict Gluten Free diet for life and moreover for a cure. Instead, Secretary Azar presided over a continued period of historic underfunding of Celiac research that was disproportionate to its prevalence, treatment burden and lack of any other treatment options. Toward the end of his tenure, Secretary Azar focused on finalizing the Gluten Free labeling rule for foods containing fermented hydrolyzed ingredients, yet he seemed did not act on calls for labeling Gluten as a Major Food Allergen which would have had a much more meaningful impact for consumer protection for millions of American Celiacs.²⁷⁹ Instead, Secretary Azar’s actions seemingly doubled-down on these biases: 1) A Gluten Free diet is all that is needed to treat Celiac Disease, as opposed to all that has ever been historically available to treat Celiac Disease, and 2) With respect to labeling food products in the United States, the voluntary Gluten Free labeling scheme sufficiently protects consumers who are on medically required and very restrictive Gluten Free diets, as opposed to all that has ever been historically utilized labeling-wise.
- **Gaslighting Gluten** – The Federal government has historically gaslighted Gluten as a second class food allergen and Celiac as not a food allergy when it comes to consumer protection with labeling Gluten as a Major Food Allergen in the US.²⁸⁰ Biomedically, conversationally and legally, it is time for regulators, scientists, doctors, consumers and the food allergy community (even including the Celiac community) to stop gaslighting Gluten. As Mark Twain said, “The difference between the right word and the almost right word is the difference between lightning and a lightning bug.” With respect to the consumer protection needs of the Celiac community with food labeling, Celiac Disease is a food allergy and Gluten is a food allergen. Period. Full Stop.
- **Federal Funding & Bias Via Blind Spots** - Funding various agencies, facilities, schools, programs, etc. that exclude Celiacs from full and equal participation in life’s daily activities that involve food, etc. Even though the Biden-Harris Administration, which has celebrated inclusivity and accommodations for many marginalized and underserved communities, has unfortunately fallen short for those with potentially life-threatening food allergies including Celiacs.²⁸¹ For example, President Joe Biden’s M&M’s epitomize the need to label Gluten as a Major Food Allergen to eliminate fear and danger.²⁸² The Washington Post reported that

²⁷⁷ https://www.dietaryguidelines.gov/sites/default/files/2020-12/Dietary_Guidelines_for_Americans_2020-2025.pdf

²⁷⁸ <https://www.fda.gov/news-events/press-announcements/fda-finalizes-rule-related-gluten-free-labeling-foods-containing-fermented-hydrolyzed-ingredients>

²⁷⁹ <https://celiacjourney.com/azar>

²⁸⁰ [www.celiacjourney.com/gaslighting](https://celiacjourney.com/gaslighting)

²⁸¹ <https://www.celiacjourney.com/whitehouse2>

²⁸² www.celiacjourney.com/mms

the “White House Easter Egg Roll celebrates education, inclusivity.”²⁸³ However, our lived experience in attending the 2023 Easter Egg Roll was that the event fell way short of accommodating those with food allergies, including Celiac.²⁸⁴

G. Universal Declaration of Human Rights - The Right to Feed Oneself in Dignity

The Preamble to the Universal Declaration of Human Rights is predicated in part on “the dignity and worth of the human person” and “the inherent dignity and of the equal and inalienable rights of all members of the human family.”²⁸⁵ To those ends, the intent of the United Nations Charter is to “promote social progress and better standards of life...”²⁸⁶

As a preface, for Celiac Disease patients and their caretakers, the “right to feed oneself in dignity” underpins the human right to adequate (safe) food,²⁸⁷ and these rights can be greatly impacted by perpetual circumstances including:

- **Consuming Poison** - Being poisoned by the consumption of Gluten (i.e., being “glutened”) and suffering from a myriad of symptoms including vomiting, diarrhea, cramping, joint pain, fatigue, brain fog, etc. (and not having any medicine that can stop, mitigate, or treat the autoimmune cascade response triggered from the ingestion of Gluten). In addition, there is the constant anxiety about the potential for cross-contact.²⁸⁸
- **Anxiety** - Worrying about cross contact with every bite, every day with short term sickness and long-term damage to one’s small intestine.
- **Food Insecurity** - Scrutinizing voluntary Gluten Free labeling and other food labels for accurate and comprehensive ingredient lists.
- **Food Insecurity** - Navigating various food label disclaimers (i.e., there are no Gluten containing ingredients, but the product has not been tested for Gluten and/or may be at risk for Gluten cross-contamination due to the way it was manufactured or processed).
- **Hunger** - Being hungry and not being able to find safe Gluten Free food options (i.e., eating away from home including at school or work and while travelling).
- **Gluten Free Tax** - Affording the high cost of the Gluten Free diet and being able to maintain adherence to the Gluten Free diet due to high cost and availability challenges, which can then lead to further serious adverse health complications.
- **Stigma - Being stigmatized and feeling isolated from not fully participating in economic (professional), social, civic, and/or educational activities that involve food, often with no**

²⁸³ <https://www.washingtonpost.com/dc-md-va/2023/04/10/white-house-easter-egg-roll/>

²⁸⁴ <https://www.instagram.com/p/Cq8P-NKLeIU/>

²⁸⁵ “Universal Declaration of Human Rights,” United Nations. 10 December 1948.

https://www.ohchr.org/EN/UDHR/Documents/UDHR_Translations/eng.pdf

²⁸⁶ <https://www.ohchr.org/en/development/milestone-events-right-development#>

²⁸⁷ <https://www.ohchr.org/sites/default/files/Documents/Publications/FactSheet34en.pdf>

²⁸⁸ <https://www.instagram.com/p/CqnYV7lrRR4/>

Celiac safe Gluten Free options.^{289 290} According to Dr. Priyanka Chugh, “The feeling of being bullied and stigmatized does not end as children age into adults: bullying and a sense of loneliness are ubiquitous in many of the lives of those with food restrictions.”²⁹¹

- **Othered** - Having the medical requirements of a strict Gluten Free diet not be taken as seriously as the medical requirements with the Major Food Allergens by government and society.

In one such example in 2016, Jennifer Harris Hopkins, was incarcerated at a New Mexico state prison, and although she reported to the prison officials that she had Celiac Disease and required a strict Gluten Free diet, she was denied that accommodation. “In the months that followed, Harris Hopkins allegedly told medical staff at the correctional facility repeatedly she was suffering from symptoms associated with the disease, which, according to the National Institutes of Health, is triggered by eating foods with gluten. ‘I am malnourished [sic – malnourished] and vitamin deficient, she wrote in a grievance with the state Corrections Department in July of that year. The items above can kill me. HELP ME!’ Two months later, Harris Hopkins was dead and the Office of the Medical Investigator found evidence of profound malnutrition from untreated celiac disease, a chronic digestive and immune disorder that damages the small intestine.”²⁹²

H. UN’s Convention on the Rights of the Child

According to the **United Nations “Convention on the Rights of the Child”**:²⁹³

- “In all actions concerning children, whether undertaken by public or private social welfare institutions, courts of law, **administrative authorities** or legislative bodies, **the best interests of the child shall be a primary consideration.**” (emphasis added) (Article 3.1)

²⁸⁹ “**Along with the high prevalence of depression and anxiety symptoms for people diagnosed with celiac disease, there also is social stigma of being diagnosed with celiac as well.** Social scientists define stigmatized persons as ‘any individual who possesses a characteristic, temporary or permanent, that other individuals view as unfavorable, negative, or unacceptable’ (Schroeder & Mowen, 2014, p. 475). Stigmatized individuals are more likely to suffer from low levels of self-esteem, increased rates of depression and anxiety, alcohol use, and other psychological issues including increased feelings of anger and hostility. Related to health stigmas, studies have found that individuals with chronic diseases, such as cancer and epilepsy, become significantly more likely to develop depression and negative self-perception at the point their chronic disease becomes a dominant aspect in their life (Schroeder & Mowen, 2014).

People with celiac disease often suffer from stigma, feelings of inadequacy, and exclusion from normal social roles. Stigmas also interfere with maintaining positive self-concepts, which tends to lead to reduction in social network and support systems.” Source: VISTAS

Online, “Celiac Disease: Depression, Anxiety, Social Stigma, and Implications for Counselors” by Rachelle Buchanan and John Arman

<https://www.counseling.org/docs/default-source/vistas/celiac-disease-depression-anxiety-social-stigma-and-implications-for-counselors.pdf?sfvrsn=8>

²⁹⁰ <https://www.aafa.org/wp-content/uploads/2022/08/aafa-my-life-with-food-allergy-parent-survey-report.pdf>

²⁹¹ https://www.huffpost.com/entry/living-with-food-allergies_b_4480918

²⁹² https://www.santafenewmexican.com/news/local_news/new-mexico-pays-200k-to-settle-wrongful-death-lawsuit-involving-prison-inmate/article_1e042f94-dd3e-11ed-972c-1f310f66503c.html

²⁹³ <https://www.ohchr.org/sites/default/files/Documents/ProfessionalInterest/crc.pdf>

- “States Parties **recognize the right of the child to the enjoyment of the highest attainable standard of health** and to facilities for the treatment of illness and rehabilitation of health. States Parties shall strive to ensure that no child is deprived of his or her right of access to such health care services.” (Article 24.1)

To address the historical inadequacies and dangers with the voluntary labeling Gluten and the underfunding of Celiac Disease, including with Federal research funding, the “legislative bodies” such as the U.S. Congress and the “administrative authorities” such as the President, HHS, FDA, NIH and CDC should use the Convention on the Rights of the Child as a guiding principle: “the best interests of the child shall be a primary consideration.”²⁹⁴

I. Celiacs Have Been Denied Opportunity to Participate Fully in Economic, Social & Civic Life

Accordingly, our Celiac community regularly shares their lived experiences of how they have **systematically been denied the opportunity to participate fully in aspects of economic, social, and civic life** when by way of example and not limitation:

- **Major Life Activities Impacted** - Celiacs are glutened regularly and have their major life activities such as eating, sleeping, thinking and/or learning impacted on an ongoing basis. Beyond Celiac reported that 44% of people with Celiac Disease who follow a strict Gluten Free diet still get glutened once a month.²⁹⁵
- **Ongoing Symptoms on a Strict Gluten Free Diet** - According to Digestive Disease Week, even when on a strict Gluten Free diet “more than half of those with Celiac Disease remained symptomatic during the five years after diagnosis.”²⁹⁶
- **Constant Anxiety and Questioning** - Celiacs constantly question food labels for inadequate and incomplete ingredient lists.
- **Food Prices for Gluten Free Food Are Disproportionately Higher** - Celiacs spend 2x-6x more on Gluten Free food products when compared to the food products’ Gluten containing counterparts, on both a per unit price and per ounce price.^{297 298} See Section XI. in this Citizen Petition entitled “The Economics of Celiac Disease with The Consumer Financial Burden of the Gluten Free Diet.”
- **Military Disqualification** - Celiacs cannot serve in the U.S. military. On the one hand, Celiac is a serious enough medical condition for the Department of Defense to disqualify Celiacs from military service in the U.S.,²⁹⁹ but on the other hand, it is not serious enough for the FDA to require the labeling of Gluten on all packaged foods.

²⁹⁴ <https://www.ohchr.org/sites/default/files/Documents/ProfessionalInterest/crc.pdf>

²⁹⁵ <https://twitter.com/abast/status/1551780196243603457>

²⁹⁶ <https://www.beyondceliac.org/research-news/five-years-after-diagnosis-more-than-half-have-symptoms/>

²⁹⁷ FDA Comment ID: FDA-2021-N-0553-1584, FDA Tracking Number l6w-qe9m-4tjy, https://downloads.regulations.gov/FDA-2021-N-0553-1584/attachment_1.pdf, pages 130-143.

²⁹⁸ <https://www.celiacjourney.com/readout>

²⁹⁹

https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/613003_vol11.PDF?ver=7fhqacc0jGX_R9_1iexudA%3d%3d

- **Treatment Burden** - Celiacs report a higher negative impact on their quality of life (treatment burden) than do people with Type 2 Diabetes, congestive heart failure, hypertension, and inflammatory bowel disease.³⁰⁰ Celiac patients report that they miss, on average, 23 days of work and school annually, resulting in excess utilization of our healthcare resources.³⁰¹
- **Choosing Schools, Camps & Colleges on Safe Food Criteria** - Celiacs and/or their parents and caretakers select an educational institution (K-12, college, university, etc.) or camp based on whether they believe that the school/camp can safely accommodate their dietary requirements, and they can eat safely at that their school (this is in addition to the “typical” criteria such as academics, athletics, location, major(s), size, cost, location, culture, professional pathway, etc.).³⁰²

Celiac students are often required to pay for meal plans at their selected college, even if there are not Celiac-safe options for them to consume and/or they get sick from being glutened due to cross contamination. There are numerous lived experience accounts including from student newspapers and litigation dockets of the failures at various schools to keep Celiac students safe, included and nourished, including at Harvard,³⁰³ University of Maryland,³⁰⁴ UCLA,³⁰⁵ University of Pennsylvania,³⁰⁶ Williams,³⁰⁷ Yale,³⁰⁸ etc.

On September 5, 2023, The New York Times reported about food allergies on college campuses,

³⁰⁰ “Patient Perception of Treatment Burden is High in Celiac Disease Compared to Other Common Conditions,” PMC, National Library of Medicine, National Institutes of Health, Shah, S., Akbari, M., Vanga, R., Kelly, C. P., Hansen, J., Theethira, T., Tariq, S., Dennis, M., & Leffler, D. A. (2014). *The American journal of gastroenterology*, 109(9), 13041311.

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4159418/> <https://doi.org/10.1038/ajg.2014.29> ; and “What is Celiac Disease?”, Celiac Disease Foundation, <https://celiac.org/about-celiac-disease/what-is-celiac-disease/> ; <https://www.beyondceliac.org/invisible-illness-infographic/> .

³⁰¹ Testimony of Marilyn G. Geller, CEO, Celiac Disease Foundation (Los Angeles, CA), to the U.S. House of Representatives Committee on Appropriations, Subcommittee on Labor, Health and Human Services, Education, and Related Agencies, April 9, 2019, <https://celiac.org/april-2019-congressional-testimony-by-ceo-marilyn-g-geller/>.

³⁰² <https://www.celiackidsconnection.org/2016/11/13/choosing-a-college/> ; <https://educationaladvocates.com/navigating-the-college-search-for-student-with-celiac-disease-and-food-allergies/> ;

<https://www.gfreefriends.com/post/celiac-complicates-your-college-search> ; and <https://www.beyondceliac.org/wp-content/uploads/2020/08/College-Toolkit.pdf>

³⁰³ <https://www.thecrimson.com/article/2020/2/14/graham-when-dining-is-dangerous/>

³⁰⁴ Hannah Smith v. University of Maryland, College Park, U.S. District Court for the District of Maryland, Case 8:20-cv-00433, Doc 1, February 20, 2020.

³⁰⁵ <https://dailybruin.com/2019/01/24/ucla-dining-services-fails-students-with-insufficient-gluten-free-considerations>

³⁰⁶ <https://www.thedp.com/article/2016/03/freshman-celiac-disease-meal-plan-dining>

³⁰⁷ <https://williamsrecord.com/457920/opinions/the-struggles-of-following-a-special-diet-at-the-college/>

³⁰⁸ <https://yaledailynews.com/blog/2020/02/10/gluten-intolerant-students-navigate-dining-halls/>

“During the first semester of her sophomore year, Maria Bambrick-Santoyo, a senior at Yale University who has celiac disease, said there were only six days when she didn’t get sick from what she ate in the dining hall... After several months of emailing college officials, she was allowed to opt out of the meal plan.”³⁰⁹ (emphasis added)

“Erica Kem, who graduated from the University of Virginia in May, has a long list of allergies: tree nuts, seafood, peanuts, coconut, dairy, eggs, wheat, barley, sesame, beef, mustard and tomatoes. The last four weren’t addressed in the allergen-free dining hall.

The staff offered to make her custom meals, but required several hours’ notice, and with her busy schedule, she couldn’t always predict when she would eat. She couldn’t decide on the spur of the moment to socialize with her friends at the dining hall without examining the menu first.

“I would have to look ahead and be like: ‘Would I actually like it? Is it worth potential contamination?’” she said. If her parents, who live a two-hour drive away, hadn’t regularly brought her home-cooked food, she would have struggled to feed herself, she said.”³¹⁰ (emphasis added)

- **Social Life** - Celiacs have been systematically denied a full opportunity to participate in aspects of social life. Think about the number of life’s activities that involve food, many of which occur spontaneously.
 - According to an FDA, “Impactful symptoms: The celiac patients and caregivers described a variety of symptoms that impact their daily life:... Patients have found it difficult to participate in social activities that involve food and beverages because of the risk of accidental ingestion of gluten or cross-contamination in food preparation. Patients will often pack their own food when eating outside of their homes, but this can be challenging with travel. Patients cannot always trust gluten-free options at restaurants.”³¹¹
 - “Food and socializing are very intimately intertwined, and it is always a bummer to be excluded from the food portion, as one then has to make a choice between being present and hungry or absent while taking care of one’s own needs.”³¹²
 - In a national benchmarking survey conducted on behalf of Beyond Celiac by The Harris Poll from February 8-10, 2022 among 2,039 adults, research showed that 53% of Americans say that foods are not always clearly labeled as gluten-free or not,

³⁰⁹ The New Reality for College Dining Halls: Dozens of Dietary Restrictions, The New York Times," Priya Krishna, September 5, 2023,

<https://www.nytimes.com/2023/09/05/dining/college-dining-halls-allergies-restrictions.html?>

³¹⁰ The New Reality for College Dining Halls: Dozens of Dietary Restrictions, The New York Times," Priya Krishna, September 5, 2023,

<https://www.nytimes.com/2023/09/05/dining/college-dining-halls-allergies-restrictions.html?>

³¹¹ <https://www.fda.gov/media/127706/download>

³¹² <https://medium.com/@bethleyba/navigating-ableism-with-invisible-disabilities-82636c50a09c>

and 53% of Americans know it can be hard to find Gluten Free food options when away from home, including at school and when travelling.³¹³

- **Career Choices** - Celiacs cannot pursue certain careers when they must eat out all the time and cannot safely and effectively control their diet. On May 29, 2020, Marilyn Geller, CEO of the Celiac Disease Foundation, informed the NIH/NIAID's Celiac Disease-Focused Autoimmune Disease Coordinating Committee about her 26-year-old son Henry's experience in college and as a travelling consultant, "And then he [Henry] unfortunately had to make the decision to switch careers because as he said, in this particular line of work where you have to eat out all the time, it was absolutely impossible. So, while I thought over the last eight years, we'd figured it out, you know, it's still coming back to the fact that as an adult his actual career choices are dependent upon whether or not he can eat safely."³¹⁴ (emphasis added)
- **Travel Limitations and Obstacles** - Celiacs cannot travel as freely as others without food allergies since they do not know where their next safe meal away from home will come from since our travel infrastructure including airports and highway rest stops are inequitable in terms of not providing safe Gluten Free food to eat.³¹⁵
- **Oral Health & Dental Defects** - According to the NIH's National Institute of Diabetes and Digestive Diseases and Kidney Diseases, "Dental enamel problems stemming from celiac disease involve permanent dentition and include tooth discoloration—white, yellow, or brown spots on the teeth—poor enamel formation, pitting or banding of teeth, and mottled or translucent-looking teeth. The imperfections are symmetrical and often appear on the incisors and molars."³¹⁶ In other words, in addition to Celiacs constantly facing food insecurity, Celiacs also have dental problems that can cause translucent teeth and chipping, even in a 10 year old boy like my son.³¹⁷ In a Cigna Dental Report published in November 2019 entitled "Behind the Smile, Oral Health Impacts Self-Esteem, Confidence and Employability," Cigna found that, "The impact that oral health and one's feelings about their smile has on self-confidence is alarming. But the cause and effect of oral health and smile satisfaction doesn't stop at self-confidence. The insecurities about smiles and oral health have had a direct impact on employment opportunities for many of the people included in this study." In addition, the study found, "It's clear there is a connection between oral health and smile satisfaction, and how confident people feel. And this connection can have a direct impact on a person's life,

³¹³ "The Mystery of Celiac Disease: The Need for Greater Awareness and Accelerating the Quest for a Cure", May 2022,

<https://www.beyondceliac.org/wp-content/uploads/2022/05/2022-Beyond-Celiac-Survey-FINAL.pdf> . Note that "[t]he sampling precision of Harris online polls is measured by using a Bayesian credible interval. For this study, the sample data is accurate to within + 2.8 percentage points using a 95% confidence level. For complete survey methodology, including weighting variables and subgroup sample sizes, please contact cbaker@beyondceliac.org."

³¹⁴ Celiac Disease-Focused Autoimmune Disease Coordinating Committee Meeting May 29, 2020, time stamp: 32:10-33:57, <https://www.dropbox.com/s/lb8ztfpyw1or2q1/ADCC%2005292020%20Zoom%20Meeting%20Recording%205-29-20.mp4?dl=0>

³¹⁵ www.celiacjourney.com/pete

³¹⁶ <https://www.niddk.nih.gov/health-information/professionals/clinical-tools-patient-management/digestive-diseases/dental-enamel-defects-celiac-disease>

³¹⁷ <https://pubmed.ncbi.nlm.nih.gov/19687752/>

including lower employability, lower levels of satisfaction with their appearance, and an increased sense of stress or discomfort in a variety of settings because of how they feel about their smile or oral health.”³¹⁸

- **Dating & Intimacy** - Celiacs carry a very heavy social burden in the dating world whereby almost half of people 18 years and older who have experienced dating hesitate to go on dates. One in five Celiacs surveyed said the overall dating experience is not enjoyable. Nearly 40 percent are uncomfortable on a date when they have to explain their need for Gluten Free food to restaurant servers. Nearly 30 percent take risks when eating and eight percent have eaten gluten knowingly. Young adults, those 23 to 35 years old reported a moderate to major impact on their lives (as compared to those older than 65 years). “Among about 600 survey participants who answered these specific questions, about 40 percent are hesitant to kiss, about 23 percent feel symptoms interfere with being physically intimate and 12 percent feel their partner needs to be on a gluten-free diet.”³¹⁹
- **Reproduction** – Pregnant women with Celiac Disease are at an increased risk of a number of negative outcomes, including preeclampsia, placental diseases, obstetric complications, and small for gestational age offspring.³²⁰ In research on the “Impact of Celiac Disease on the Maternal and Fetal Outcomes,” the “study indicates that pregnant women with CD are at higher risk for both maternal and fetal complications and this is statistically significant.”³²¹
- **Celiac Children and Adults Are Bullied** - Celiacs are often bullied because of their food allergy³²²; About one-third of kids with food allergies report that they have been bullied because of their allergies, including my 10-year-old son.
- **Stigma: Celiacs Are Thought of as Attention Seekers** – According to a nationwide survey conducted online among 2,081 U.S. adults April 11-13, 2023, by the Harris Poll on behalf of Beyond Celiac, “28% of Americans strongly/somewhat agree that people who eat gluten-free are just trying to get attention.”³²³ When the medical needs of the Celiac community are not taken seriously by the Federal government, it is no wonder that so many Americans conflate the voluntary labeling of Gluten with the voluntary adoption of a Gluten Free lifestyle and therefore view Celiacs as attention seekers.
- **Stigma: A Strict Gluten Free Diet is for Weight Loss (and Not Medically Required Diet to Treat a Food Allergy and Auto-Immune Disease)** - According to a nationwide survey conducted online among 2,081 U.S. adults April 11-13, 2023, by the Harris Poll on behalf of

³¹⁸ https://images.connecting.cigna.com/Web/CIGNACorporation/%7B1068fec3-a6d7-48c1-9664-05ccebba3710%7D_930138_Self_Esteem_Article_Dental_flyer.pdf

³¹⁹ <https://www.beyondceliac.org/research-news/dating-doesnt-read-like-romantic-novel/>

³²⁰ <https://www.hcplive.com/view/jansson-knodell-treating-pregnant-women-celiac-disease>

³²¹ <https://eposters.ddw.org/ddw/2022/ddw-2022/354019/maryam.haider.impact.of.celiac.disease.on.the.maternal.and.fetal.outcomes.html?>

³²² <https://glutendude.com/party-city-calls-celiacs-gross/>

³²³ <https://www.beyondceliac.org/wp-content/uploads/2023/06/2023-Beyond-Celiac-Harris-Report-06.23-1.pdf>

Beyond Celiac, “57% of Americans strongly/somewhat agree that many people following a gluten-free diet are trying to lose weight.”³²⁴

- **Stigma: Misperception That Celiacs Are “Generally Healthier” Than Those Who Do Not Have Celiac** - Even though Celiacs must eat a strict Gluten Free diet since they have a potentially life-threatening and life-debilitating food allergy and auto-immune disease triggered by eating Gluten, “49% of Americans strongly/somewhat agree that people who eat gluten-free are generally healthier than those people who eat gluten.”³²⁵ This suggests that almost one-half of all Americans believe that Celiacs are generally healthier than people who eat Gluten and do not have Celiac Disease. Imagine how preposterous it would sound if 49% of Americans believed that those who required insulin were healthier than people who do not have Diabetes.
- **Celiacs Are Ridiculed** - The only available treatment for Celiac – a strict lifetime Gluten Free diet – and Celiacs are too often the punchline of jokes in the media and entertainment industries.³²⁶ On February 2, 2015, Maura Judkis from the Washington Post helped normalize and popularize making fun of the Gluten Free diet in an article entitled, “Nick Offerman pitches NASCAR in hilarious Super Bowl 2015 commercial” when she wrote,

“The premise: America’s favorite lumbersexual, Nick Offerman, makes the pitch for NASCAR, which is a genius casting move: His red meat-eating, wilderness-loving ways are in lockstep with NASCAR’s typical audience, but he’s beloved by Millennial urbanites, who are less likely to be interested in watching cars zoom around a track, unless they’re doing it ironically.

The punchline: He kicks it off by imploring Americans to do a gut-check: When our idea of danger is eating gluten, there’s trouble afoot. Then, Offerman teaches us how to be a True American Patriot in a series of vignettes that would make our Founding Fathers proud...”³²⁷ (emphasis added)

J. Historical Context of Celiacs Being Underserved and Marginalized by the Federal Government

To better understand the history of how the Celiac community has been underserved, please see the [Comments](#) of Bari Consulting Group, Celiac Journey and Gluten Free Finds to the FDA’s Draft Guidance, August 16, 2022 (“Bari Comments”) including these key excerpts (some of which have been summarized in this Citizen Petition):

³²⁴ <https://www.beyondceliac.org/wp-content/uploads/2023/06/2023-Beyond-Celiac-Harris-Report-06.23-1.pdf>

³²⁵ <https://www.beyondceliac.org/wp-content/uploads/2023/06/2023-Beyond-Celiac-Harris-Report-06.23-1.pdf>

³²⁶ By way of example, see www.celiacjourney.com/mean
<https://glutendude.com/why-the-jimmy-kimmel-video-matters/>
<https://glutendude.com/netflix-do-revenge-celiac/>
<https://glutendude.com/barstool-sports-gluten-free-people-are-weak/>
<https://glutendude.com/grinch-ad-campaign-gluten/>

³²⁷ <https://www.washingtonpost.com/news/arts-and-entertainment/wp/2015/02/02/nick-offerman-pitches-nascar-in-hilarious-super-bowl-2015-commercial/>

- **“Section I – Executive Summary”**³²⁸ (pages 3-12)
- **“Section I [sic] Preliminary Statement on the Food Allergen Labeling and Consumer Protection Act”**³²⁹ (Bari Comments, pages 12-16) – Included in this section are details on how the FALCPA does not define “allergy”, “food allergy”, “allergen”, “allergic reaction” or “major allergen”. FALCPA also does not mention “immunoglobulin E”, “IgE”, “IgE-Mediated”, “Non-IgE-Mediated” “antibodies” or “anaphylaxis.” Moreover, there is no express requirement in the FALCPA that a “Major Food Allergen” must include symptoms compatible with IgE-mediated mechanisms, including anaphylaxis (see discussion in this Citizen Petition regarding the 2008 Citizen Petition seeking to label Gluten and the FDA’s Draft Guidance).
- **“Section VIII – What’s in A Name? Celiac is a Food Allergy!”** (Bari Comments, pages 50-68)³³⁰ – please pay special attention to page 56 in the Bari Comments on the “History of Food Allergy Terminology” which cites detailed research from Dr. Matthew Smith’s book “Another Person’s Poison” on how the “orthodox allergists” worked to define food allergy in the US as limited to IgE-Mediated reactions that can cause anaphylaxis and in turn excluded Celiac Disease, which is a Non-IgE-Mediated food allergy, from the same consumer protections as IgE-Mediated food allergies.³³¹

According to Dr. Smith, the orthodox allergist movement was “represented by the AAAAI” and “worked with the food industry to reinforce their narrow definition of food allergy, a definition that was epitomized by peanut allergy. Forgotten in the focus on the acute, anaphylactic reaction to foods that food allergists had long argued were more common and problematic. Although some of these patients’ problems came to be understood in terms of intolerances to lactose or gluten, symptoms connected with food additives and refined foods continued to be viewed with suspicion in the face of mounting evidence that they could be harmful. Despite making food allergy a legitimate health concern, the rise of peanut allergy also helped to transform food allergy into a very specific, attenuated, and limited phenomenon, adhering to the way orthodox allergists had defined it all along.”³³²

Also, see article entitled, “Let’s Stop Gaslighting Gluten as a Second-Class Food Allergen & Celiac as Not a Food Allergy!”³³³

- **“Section X – FALCPA Fell Short in Protecting Celiacs”** (Bari Comments, pages 72-79)³³⁴
- It is instructive to note that when FALCPA was introduced by Senator Ted Kennedy (D,

³²⁸ FDA Comment ID: FDA-2021-N-0553-1584, FDA Tracking Number l6w-qe9m-4tjy, https://downloads.regulations.gov/FDA-2021-N-0553-1584/attachment_1.pdf

³²⁹ FDA Comment ID: FDA-2021-N-0553-1584, FDA Tracking Number l6w-qe9m-4tjy, https://downloads.regulations.gov/FDA-2021-N-0553-1584/attachment_1.pdf

³³⁰ FDA Comment ID: FDA-2021-N-0553-1584, FDA Tracking Number l6w-qe9m-4tjy, https://downloads.regulations.gov/FDA-2021-N-0553-1584/attachment_1.pdf

³³¹ <https://celiacjourney.com/gaslighting>

³³² Smith, Matthew. “Another Person’s Poison: A History of Food Allergy.” New York: Columbia University Press, 2015. Print, pages 155-156.

³³³ <https://www.celiacjourney.com/gaslighting>

³³⁴ FDA Comment ID: FDA-2021-N-0553-1584, FDA Tracking Number l6w-qe9m-4tjy, https://downloads.regulations.gov/FDA-2021-N-0553-1584/attachment_1.pdf

MA), Senator Hillary Clinton (D, NY)³³⁵ and Rep. Nita Lowey (D, NY-18),³³⁶ FALCPA included express language to require the labeling of Gluten as a Major Food Allergen on all packaged foods. However, on August 9, 2002, “Inside Washington’s FDA Week” reported that Senator Kennedy floated an amendment to the FALCPA,

“But the food industry source says that even though the amendment goes in the right direction, the food industry continues to oppose the bill on the grounds that a mandatory approach is not appropriate or needed, and that instead the food industry should be allowed to continue to implement its voluntary guidelines... **Critics of the bill [in the food industry and “orthodox” allergists] had charged that scientifically, Gluten is an intolerance not an allergen.**”³³⁷ (emphasis added)

This was a false premise which was unfortunately not rebutted circa 2002, and it ultimately gained strength and support, even though it was dangerously and scientifically inaccurate, and incongruent with the 1999 Codex Criteria. The lobbyists conflated Celiac Disease (a potentially life-threatening food allergy, auto-immune disease and digestive disease) with Gluten intolerance (i.e., a non-immune-mediated sensitivity that “is inconvenient but not life-threatening” like lactose intolerance³³⁸).

According to Inside Washington’s (Health Policy’s) “FDA Week”, September 27, 2002 (page 5),

“Substitute [bill] pulls mandatory Gluten declaration... This week the Senate Health Committee passed without objection a watered-down version of a bill that would require food processors to label the eight most common types of food allergens in plain English. **The substitute version, unlike the underlying bill... would not require the declaration of Gluten.**”³³⁹ (emphasis added)

- **“Section XI – The FDA Fell Short for a Decade in Protecting the Celiac Community”** (Bari Comments, pages 79-96)³⁴⁰ – This section includes a detailed historical analysis including how there was a Citizen Petition filed on September 10, 2008 to label Gluten and how the FDA took a decade to then deny this request summarily “because the petition did not include adequate information to show that rye and barley are common causes of severe IgE-mediated food allergies (Ref. 22).”³⁴¹ (see pages 90-91)

³³⁵ <https://www.congress.gov/bill/107th-congress/senate-bill/2499/summary/00>

³³⁶ <https://www.congress.gov/bill/107th-congress/house-bill/4704>

³³⁷ https://fd19a27e-adc0-4b2e-a80e-88598593a644.usrfiles.com/ugd/fd19a2_3b58cb1248eb41e8bff67c2c2c3c2f80.pdf

³³⁸ <https://my.clevelandclinic.org/health/diseases/21688-food-intolerance>

³³⁹ https://fd19a27e-adc0-4b2e-a80e-88598593a644.usrfiles.com/ugd/fd19a2_e352e90b251941a1a5482f10f835f7c8.pdf

³⁴⁰ FDA Comment ID: FDA-2021-N-0553-1584, FDA Tracking Number l6w-qe9m-4tjy, https://downloads.regulations.gov/FDA-2021-N-0553-1584/attachment_1.pdf

³⁴¹ FDAs Draft Guidance, and Ref. 18: Citizen Petition CP-2008-P-0509, received September 10, 2008, submitted by Hallie Jane Davis, Docket No. FDA-2008-P-0509, Document ID FDA-2008-P-0509-0001 and Ref. 22: Letter dated February 6, 2018, from Douglas Stearn of FDA to Hallie Jane Davis. Available at <https://www.regulations.gov>, Docket No. FDA-2008-P-0509, Document ID FDA-2008-P-0509-0007, https://downloads.regulations.gov/FDA-2008-P-0509-0001/attachment_1.pdf ; <https://www.regulations.gov/docket/FDA-2008-P-0509/document>

September 10, 2008: Citizen Petition to Label Barley and Rye in 2008

According to the FDA's Draft Guidance,

“In 2008 [September 10], we [FDA] received a citizen petition [submitted by Hallie Jane Davis] asking us to [amend] ... FALCPA to include barley and rye in the list of common allergens requiring disclosure on packaging (Ref. 18)³⁴²... In 2018 [February 6], **“We [FDA] denied the request regarding barley and rye because the petition did not include adequate information to show that rye and barley are common causes of severe IgE-mediated food allergies** (Ref. 22).”³⁴³ (emphasis added)

First, it is important to note that there was a 10-year delay from 2008-2018 (encompassing three different Presidential administrations for President George W. Bush, 2001-2009; President Barack Obama, 2009-2017; and President Donald Trump, 2017-2021) for the FDA to summarily deny the citizen petition based on a pretext “because the petition did not include adequate information to show that rye and barley are common causes of severe IgE-mediated food allergies.”

On February 6, 2018 (in response to the citizen petition filed almost a decade earlier by Ms. Davis on September 10, 2008), Douglas Stearn Deputy Director, Center for Food Safety and Applied Nutrition, U.S. Food and Drug Administration, wrote to Ms. Davis,

“Your petition does not include adequate information to show that rye and barley are common causes of severe immunoglobulin E (IgE)-mediated allergies, such as wheat and other major food allergens under FALCPA. Rather, your petition focuses on the needs of people with celiac disease, which we have taken steps to address. Your citizen petition provides as a statement of grounds: ‘It has been shown that celiacs are not just sensitive to wheat, but are also sensitive to the gluten of rye and barley’ (Petition at page 1). **We agree with this statement and note that information voluntarily provided on food labels concerning the absence of gluten-containing grains may provide additional label information that is helpful to consumers seeking to avoid barley and rye.**”³⁴⁴ (emphasis added)

Just like the 2021 FAO/WHO Expert Consultation including Dr. Lauren Jackson, Dr. Stefano Luccioli, Dr. Joseph Baumert, and Dr. Stephen Taylor did not adversely distinguish between IgE-Mediated and Non-IgE-Mediated food allergies in their systematic and thorough assessments which used all three criteria (prevalence, severity and potency) to determine the Risk Assessment of Food Allergens, the FDA must stop discriminating between IgE-Mediated and Non-IgE-Mediated food allergies with Celiac when it comes to equitably evaluating the labeling of Gluten as a Major Food Allergen to protect 3.3 million American Celiacs.

³⁴² https://downloads.regulations.gov/FDA-2008-P-0509-0001/attachment_1.pdf

³⁴³ FDA's Draft Guidance, and Ref. 18: Citizen Petition CP-2008-P-0509, received September 10, 2008, submitted by Hallie Jane Davis, Docket No. FDA-2008-P-0509, Document ID FDA-2008-P-0509-0001 and Ref. 22: Letter dated February 6, 2018, from Douglas Stearn of FDA to Hallie Jane Davis. Available at <https://www.regulations.gov>, Docket No. FDA-2008-P-0509, Document ID FDA-2008-P-0509-0007, <https://www.regulations.gov/docket/FDA-2008-P-0509/document>, https://downloads.regulations.gov/FDA-2008-P-0509-0001/attachment_1.pdf

³⁴⁴ https://downloads.regulations.gov/FDA-2008-P-0509-0008/attachment_1.pdf

In her 2008 citizen petition, Ms. Davis did provide a lot of medical and scientific research showing the severe adverse health effects that can occur when Celiacs ingest even a very small quantity (“10mg”) of Gluten including intestinal damage, cancer, failure to thrive, osteoporosis, etc. Ms. Davis also discussed and presented research on the comorbidities of Celiac with other auto-immune diseases and her lived experience with food insecurity.

Nonetheless, Mr. Stearn was dismissive in his response when he wrote, “Your petition does not include adequate information to show that rye and barley are common causes of severe immunoglobulin E (IgE)-mediated allergies, such as wheat and other major food allergens under FALCPA. Rather, your petition focuses on the needs of people with celiac disease, which we have taken steps to address.”³⁴⁵ In other words, while Ms. Davis did not include information that rye and barley are common causes of severe immunoglobulin E (IgE)-mediated allergies, she did include information to the FDA on the adverse effects that occur in Celiacs with the ingestion of Gluten and why it would be common sense to label Gluten as a Major Food Allergen, just like the 1999 Codex Criteria had recommended.

The FDA’s denial of Ms. Davis’s Citizen Petition was yet another example of the FDA gaslighting Gluten as a Second Class Food Allergen & Celiac as Not a Food Allergy!³⁴⁶

In addition to this anemic response taking 10 years, this response was tone deaf. It also suggests that it was not in compliance with the FDA’s Quality Resource and Development Team which stated,

“In carrying out its public health mission (reference #3) [FDA Mission Statement]³⁴⁷, FDA clearly understands that the American public is the primary customer of the agency’s work and the products we regulate.”³⁴⁸

In other words, this is no way to treat a customer at all. In the private sector, if the citizen petitioner, Hallie Jane Davis, was really a customer, she would have likely taken her business elsewhere due to non-responsiveness and obfuscation. Additionally, the private sector would likely not tolerate such poor customer service and untimely responses from its employees.

- **Section XX - The Only Available Treatment for Celiac Gluten Free Food Must Be Viewed as a Human Right** (pages 124-130)³⁴⁹
- **Section XXI – The Economics of Celiac Disease with the Financial Burden of the Gluten Free Diet** (pages 130-144).³⁵⁰ Please note the analysis discussing that the 2022 baby formula shortage is instructive to understand food insecurity and market forces in the context of food for those with special dietary requirements such as Gluten Free foods potentially disappearing from market shelves. From the 2022 infant formula crisis, we have learned that

³⁴⁵ https://downloads.regulations.gov/FDA-2008-P-0509-0008/attachment_1.pdf

³⁴⁶ www.celiacjourney.com/gaslighting

³⁴⁷ <http://www.fda.gov/opacom/morechoices/mission.htm>

³⁴⁸ <https://web.archive.org/web/20210309071904/https://www.fda.gov/media/77398/download>

³⁴⁹ FDA Comment ID: FDA-2021-N-0553-1584, FDA Tracking Number 16w-qe9m-4tjy, https://downloads.regulations.gov/FDA-2021-N-0553-1584/attachment_1.pdf

³⁵⁰ FDA Comment ID: FDA-2021-N-0553-1584, FDA Tracking Number 16w-qe9m-4tjy, https://downloads.regulations.gov/FDA-2021-N-0553-1584/attachment_1.pdf

markets for specialized foods (i.e., “specially formulated powders, much of it made by Abbott, to compensate for a variety of ailments, from malformed bowels and allergies to problems processing nutrients like protein”³⁵¹) can be disrupted by various factors including macro-economic, micro-economic, supply chain, and operational shock issues. Additionally, if fad diets change (as history informs us, they likely will, i.e., Scarsdale, Atkins, South Beach) and the market for Gluten Free food declines among those consumers who voluntarily elect to pay these premiums (i.e., the “Gluten Free tax”) to consume Gluten Free food, then the supply of available safe Gluten Free food will also likely shrink. Moreover, in the absence of required labeling of Gluten on all packaged foods, and in the event that the Gluten Free lifestyle market declines or fades away (i.e., people without a medical necessity), the Celiac community will be left with even fewer choices to eat adequately and safely. This will likely force prices even higher on a more limited array of Gluten Free foods.

This is another reason that Gluten should be labeled on all packaged foods in the U.S. since there are many products that are free from Gluten but just not labeled since there is no mandatory labeling scheme. In other words, this will expand consumer choice for Celiacs and serve as a potential source of increased revenues for manufacturers and retailers. (Bari Comments, pages 142-144) This echoes the argument set forth in the 2008 Gluten Labeling Citizen Petition from Ms. Davis, “The advantage for the producer is that there will be many products which we on gluten-free diets have been avoiding due to the nagging question of whether they contain rye or barley, and we will find out that many of them do not, and we really CAN buy them after all!”³⁵²

³⁵¹ <https://www.washingtonpost.com/health/2022/06/03/baby-formula-shortage-metabolic-disorder/>

³⁵² https://downloads.regulations.gov/FDA-2008-P-0509-0001/attachment_1.pdf

VI. Question: Are 90% of Food-Sensitive Americans Helped by the Food Allergen Labeling and Consumer Protection Law? Answer: NO!

**“Not everything that can be counted counts and
not everything that counts can be counted!”**

-- Albert Einstein

A. Overview

According to Footnote 6 in the FDA’s Draft Guidance,

“At the time that FALCPA was enacted, these eight foods were believed to account for 90 percent of food allergies and most serious reactions to foods (section 202(2)(A) of FALCPA (21 U.S.C. 343 note); Ref. 6 and Ref. 7). More than 160 foods are known to cause IgE-mediated food allergic reactions of varying severity, many with relatively low prevalence rates, with some as low as single cases (Ref. 7).”³⁵³

In 2006, the Food & Drug Law Journal published the seminal article entitled, “When Food Is Poison: The History, Consequences, and Limitations of the Food Allergen Labeling and Consumer Protection Act of 2004” (“When Food Is Poison”).³⁵⁴ “When Food Is Poison” answered this question in contemporaneous fashion – “Are Ninety Percent of Food-Sensitive Americans Helped by the FALCPA?”,

“The FALCPA touts a statistic that the Big Eight allergens are responsible for ninety percent of ‘food allergies.’³⁵⁵ Congress, FDA, and the media all seized on this figure that implies that the FALCPA alleviates problems faced by ninety percent of food sensitive individuals. Does the FALCPA actually help ninety percent of people with food sensitivities?

This question is worth exploring insofar as it sheds light on why the FALCPA requires the declaration of only eight foods. Also, **the meaning and accuracy of this statistic is important because it may generate a sense of complacency by FDA, the food industry, and Congress with regard to expanding the list of allergens warranting attention**; the belief that problems have been remedied for ninety percent of food sensitive individuals lessens the impetus to work to provide more widespread labeling coverage.

First, it is inaccurate to view the statistic as asserting that ninety percent of Americans with food sensitivities are helped by the FALCPA. As the term ‘food allergies’ may make plain to the initiated, **this ninety percent figure refers only to people with IgE-mediated, immediate hypersensitivity reactions to food, not to people with delayed hypersensitivity reactions such as those with celiac disease**. The ninety percent claim, thus, is an assertion limited to people with [typical] food allergies proper.

Second, the history behind this statistic reveals that it is not the case that an estimated

³⁵³ <https://www.fda.gov/media/157637/download>

³⁵⁴ Derr, Laura E. “When Food Is Poison: The History, Consequences, and Limitations of the Food Allergen Labeling and Consumer Protection Act of 2004.” *Food and Drug Law Journal*, vol. 61, no. 1, 2006, pp. 65–165. JSTOR, <https://www.jstor.org/stable/i26659390>

³⁵⁵ FALCPA 202(2)(a), 21 U.S.C.A. 343(note).

ninety percent of food-allergic people are allergic to Big Eight allergens, as the FALCPA's preamble itself suggests;³⁵⁶ rather, Big Eight allergens are responsible for about ninety percent of adverse reactions.³⁵⁷ Although ninety percent of allergic reactions may be caused by the Big Eight, that does not mean that ninety percent of allergy sufferers are helped. People could experience multiple reactions and be counted multiple

³⁵⁶ “See the imprecise language employed in the FALCPA. Section 202(2)(a) states that the Big Eight allergens ‘account for 90 percent of food *allergies*’ (emphasis added); see also, e.g., FDA, Advice to Consumers, *supra* note 5 (‘[T]he eight major food allergens identified by FALCPA account for over 90 percent of all documented food allergies in the U.S. and represent the foods most likely to result in severe or life-threatening reactions.’)” [“See S. Allan Bock et al., Fatalities Due to Anaphylactic Reactions to Foods, 107 J. Allergy Clin. Immunol. 191, 193 (2001); FDA, Advice to Consumers: Food Allergen Labeling and Consumer Protection Act of 2004, Questions and Answers (Dec. 12, 2005),

<https://web.archive.org/web/20060810114209/http://www.cfsan.fda.gov/~dms/alrgqa.html> [hereinafter FDA, Advice to Consumers] (“Approximately 30,000 consumers require emergency room treatment and 150 Americans die each year because of allergic reactions to food.”). Peanut allergies alone account for 50 to 100 deaths per year. See Teen With Peanut Allergy Dies After Kiss, Associated Press, Nov. 28, 2005, available at

<https://web.archive.org/web/20060421075602/http://www.msnbc.msn.com/id/10243950/> “

³⁵⁷ “See, e.g., H.R. 4704, 107th Cong. 2 (2d Sess. 2002) (‘Eight major foods -- milk, egg, fish, Crustacea, tree nuts, wheat, peanuts, and soy beans cause 90 percent of allergic reactions’) (emphasis added); FAO Consultation, [Report of the FAO Technical Consultation on Food Allergies, Annex 4: Consideration by Codex of Food Allergies and Hypersensitivity 4 (Nov. 13-14, [hereinafter FAO Consultation]: The current deliberations of the [Codex Committee on Food Labeling] in respect of the problem of food allergens dates from the nineteenth session in 1987 when the Committee took note of the availability of a reliable method for the determination of gliadin, which had been identified as the causative agent of gluten intolerance in celiac disease, and agreed that this and similar problems of food allergy and intolerance and their relationship to the adequacy of the ingredient listing requirements in the General Standard should be considered at a future meeting.]; Hefle et al., *supra* note 4 [“Adverse reactions vary depending on numerous factors, including the specific sensitivity, the amount of unsafe food ingested, and the individual’s particular body chemistry. See, e.g., Hugh A. Sampson & Dean D. Metcalfe, Food Allergies, 268 JAMA 2840, 2841 (1992); Susan L. Hefle et al., Allergenic Foods, 36(S) Crit. Rev. Food Sci. & Nutrition S69, S70, S81 (1996); Hugh A. Sampson, Food Allergies, 278 JAMA 1888-94 (1997) (discussing a variety of symptoms/adverse reactions associated with different types of food sensitivities); Jean Bousquet et al., Food Allergy, in Report of the Food and Agriculture Organization (FAO) Technical Consultation on Food Allergies, Annex 3, at 5-6 (Nov. 13-14, 1995) (on file with author [Ms. Derr]); see also *infra* note 78. This list includes some symptoms associated only with food allergies (e.g., anaphylaxis), some symptoms associated only with celiac disease (e.g., malabsorption and increased risk of cancer and osteoporosis), and many symptoms associated with both types of food sensitivity.”] Even though the impression left by the media and congressional debate frequently was that 90% of people with food allergies would be helped by the FALCPA, FDA tended to employ more accurate terminology that indicated that the Big Eight represent the allergens most frequently responsible for serious adverse reactions. See, e.g., 66 Fed. Reg. 38,591, 38,592 (July 25, 2001) (‘FDA’s allergen awareness efforts are currently focused on the eight foods that are most frequently implicated in serious allergic responses ...’)” (emphasis added)”

times, meaning the percent of food-allergic individuals with a Big Eight allergy actually is less than ninety.”³⁵⁸

Additionally, When Food Is Poison memorialized,

“How many allergens and which ones potentially should be subjected to mandatory disclosure was debated at the 2001 Public Meeting. When FAAN’s [The Food Allergy & Anaphylaxis Network] Munoz-Furlong asked whether the eight major allergens should be the appropriate focus of labeling whether additional efforts should be placed on less common allergens, she stated, ‘**My belief is that if we focus on the eight major allergens, we’ve covered 90 percent of problem, and once we clear that up, we should start looking in other areas**, but keep the eight so that we can focus there.’³⁵⁹ **In contrast, Dr. Michael Jacobson, co-founder and Executive Director of CSPI [Center for Science in the Public Interest], advocated for more expansive allergen disclosure, ‘We urge FDA to require disclosure not just of the major eight allergens, but others as well.’**^{360,361}

The following comments from the FDA’s Stefano Luccioli, M.D. suggest that the FDA, even as of May 5, 2021, inaccurately believe that the Big Eight allergens in 2004 were responsible for ninety percent of food allergies,

“The eight major food allergens were selected because, at the time the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) was passed, they were responsible for 90 percent of food allergies and thus were the most common causes of severe food reactions in the United States.”³⁶²

To that end, this misperception that the top 8 Major Food Allergens account for over 90% of food allergies has unfortunately helped perpetuate a sense of complacency by FDA, the food industry, and Congress with regard to expanding the list of allergens requiring attention to include Gluten. In other words, in spite of Dr. Luccioli’s great work as part of the 2021 FAO/WHO’s Expert Consultation in May 2021 and recommendations to always declare Gluten, the comments about FALCPA’s impact suggest a perpetuation of an inaccurate understanding

³⁵⁸ Derr, Laura E. “When Food Is Poison: The History, Consequences, and Limitations of the Food Allergen Labeling and Consumer Protection Act of 2004.” Food and Drug Law Journal, vol. 61, no. 1, 2006, pp. 65–165, <http://www.jstor.org/stable/26660870> . Accessed 13 May 2022.

³⁵⁹ “FDA, 2001 Public Meeting Transcript, supra note 44 [The Challenge of Labeling Food Allergens 32 (August 13, 2001)], at 106 (statement of Anne Munoz-Furlong, FAAN); see also id. at 158 (statement of Anne Munoz-Furlong, FAAN): ‘I know that there’s a study that’s been done that looked at the foods that had been implicated in reactions, and there were somewhere around 160 foods on that list. That’s an enormous task. What we would recommend again is to stay focused on the 90 percent of that problem. Once we figure out what the solutions are there, we can hopefully then quickly come by and address some of these other issues.’”

³⁶⁰ FDA, 2001 Public Meeting Transcript, supra note 44 [The Challenge of Labeling Food Allergens 32 (August 13, 2001)], at 135 (statement of Michael Jacobson, CSPI).

³⁶¹ Derr, Laura E. “When Food Is Poison: The History, Consequences, and Limitations of the Food Allergen Labeling and Consumer Protection Act of 2004.” Food and Drug Law Journal, vol. 61, no. 1, 2006, pp. 65–165, <http://www.jstor.org/stable/26660870> . Accessed 13 May 2022.

³⁶² <https://www.fda.gov/food/conversations-experts-food-topics/current-food-allergen-landscape>

and appreciation for the potentially life-threatening adverse reactions of Gluten ingestion for those with Celiac Disease.

VII. FALCPA Fell Short in Safeguarding Celiacs

“Did you know that 44% of people with celiac disease who follow a strict gluten-free diet still get glutened once a month?”³⁶³

-- Alice Bast, CEO of Beyond Celiac

“Coming from the anaphylactic egg allergy world to celiac land has been crazy. I am blown away by the crappy labeling practices for gluten.

The egg is a scary allergy but SO MUCH EASIER to shop for.”³⁶⁴

--K.S., June 2022

A. Overview – 1999 Codex Criteria

In order to understand how FALCPA muted the seriousness of Celiac Disease, it is instructive to review the history of FALCPA, as well as the 1999 FAO/WHO Expert Consultation with the 1999 Codex Criteria.

According to the Food and Agriculture Organization of the United Nations,

“The list of 8 major foods and ingredients (cereals containing gluten, crustacea, egg, fish, peanut and soybeans, milk, tree nuts) known to cause hypersensitivity [big 8 food allergens] was included into the ‘Codex General Standard for the Labelling of Packaged Foods’ (GSLPF)³⁶⁵ in 1999.”³⁶⁶

B. FALCPA’s Legislative Intent & Original Language

On May 9, 2002, Senator Ted Kennedy (D, Massachusetts) addressed the U.S. Senate:

“American families deserve to feel confident about the safety of the food on their tables... The Food Allergen Consumer Production Act will require that food ingredient statements on food packages identify in common language when an ingredient, including a flavoring, coloring, or other additive, is itself, or is derived from, one of the eight main food allergens, or from grains containing Gluten.”³⁶⁷

The clear legislative intent of the FALCPA was to protect those consumers with food allergies and Celiac Disease, both of which involve adverse reactions to proteins in food that are immune-mediated to proteins. The requirement that Gluten be labeled on all packaged foods in the U.S. was expressly contemplated in 2002 in the original versions of the FALCPA:

³⁶³ <https://twitter.com/abast/status/1551780196243603457?>

³⁶⁴ As posted on Facebook in a community group with more than 11,000 members where parents and caregivers to children with Celiac and Non-Celiac Gluten Sensitivities share their knowledge and lived experiences with other members who are similarly situated.

³⁶⁵ https://www.fao.org/fao-who-codexalimentarius/sh-proxy/pt/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXS%2B1-1985%252FCXS_001e.pdf

³⁶⁶ <https://www.fao.org/food-safety/news/news-details/fr/c/1398460/>

³⁶⁷ <https://www.govinfo.gov/content/pkg/CREC-2002-05-09/pdf/CREC-2002-05-09-senate.pdf>

- **S. 2499**³⁶⁸ – “The Food Allergen Consumer Protection Act of 2002,” as introduced by Senator Kennedy [and Senator Clinton (D, New York)], would require products to list in bold face type the common name any of the eight major food allergens (milk, egg, fish, crustacea, peanuts, tree nuts and soybean), proteins derived from those substances and other ***Glutens such as rye, barley, oats, and triticale***,” according to Inside Health Policy’s FDA Week, August 9, 2002 (page 6). (emphasis added) “For purposes of this Act, the term ‘known food allergen’ means any of the following: A) Milk, Egg, Fish, Crustacea, Tree nuts, **Wheat**, Peanuts, and Soybeans... C) ***Other Grains containing Gluten (Rye, Barley, Oats, and Triticale)***.”³⁶⁹
- **H.R. 4704**³⁷⁰ - The “Food Allergen Consumer Protection Act,” as introduced by Representative Nita Lowey (D, NY-18) in 2002, expressly included “***Grains Containing Gluten***” among the “allergens” within the scope of the legislation’s mandatory labeling scheme. H.R. 4704, 107th Cong. [Section] 3 (2d Sess. 2002). “(3) For purposes of this Act, the term ‘known food allergen’ means any of the following: (A) Milk, egg, fish, Crustacea, tree nuts, wheat, peanuts, and soybeans” and “Other grains containing gluten (rye, barley, oats, and triticale).”³⁷¹

C. Misinformation Campaign Changed FALCPA’s Protections for Celiacs

While the FALCPA was being debated in Congress, the food industry lobbied against the FALCPA in its entirety and insisted that voluntary labeling of food allergens was sufficient. However, the food industry seemingly evolved its position and recognized that there was a convergence of factors, a perfect storm, that finally gave Congress the appetite and resolve to pass the FALCPA. With that recognition, the food industry then demanded certain compromises and concessions.

On August 9, 2002, Inside Washington’s FDA Week reported that Senator Kennedy floated an amendment to the FALCPA,

“But the food industry source says that even though the amendment goes in the right direction, the food industry continues to oppose the bill on the grounds that a mandatory approach is not appropriate or needed, and that instead the food industry should be allowed to continue to implement its voluntary guidelines... **Critics of the bill [in the food industry] had charged that scientifically, Gluten is an intolerance not an allergen.**”³⁷²

This was a false premise which was unfortunately not rebutted, and it ultimately gained strength and support, even though it was dangerously and scientifically inaccurate. The lobbyists seemingly conflated Celiac Disease (a food allergy, auto-immune disease and digestive disease) with Gluten intolerance. As detailed below, information suggests that it was the American Bakers Association and/or American Farm Bureau which argued that scientifically, Gluten is an

³⁶⁸ <https://www.congress.gov/bill/107th-congress/senate-bill/2499/summary/00>

³⁶⁹ https://fd19a27e-adc0-4b2e-a80e-88598593a644.usrfiles.com/ugd/fd19a2_3b58cb1248eb41e8bff67c2c2c3c2f80.pdf

³⁷⁰ <https://www.congress.gov/bill/107th-congress/house-bill/4704>

³⁷¹ <https://www.congress.gov/bill/107th-congress/house-bill/4704>

³⁷² https://fd19a27e-adc0-4b2e-a80e-88598593a644.usrfiles.com/ugd/fd19a2_3b58cb1248eb41e8bff67c2c2c3c2f80.pdf

intolerance, not an allergen. Fast forward to 2022, and the FDA's Draft Guidance suggests that it still conflates a Gluten food allergy with lactose intolerance.³⁷³

On September 20, 2002, the Center for Science in the Public Interest (CPSI) reported that [S.2499](#) had become “stymied” in the Senate Health, Education, Labor and Pensions (HELP) Committee which was chaired by Senator Kennedy,

“Senate Democrats and Republicans have been working on compromise language to move the legislation out of the Health, Education, Labor, and Pension committee, which Senator Kennedy chairs. Even though Democrats have offered significant concessions, key Republicans on the committee have sided with the food industry, which generally opposes any labeling changes, according to CSPI.”³⁷⁴

According to When Food Is Poison,

“Most of the groups involved in advocating for the FALCPA were food allergy groups [such as FAAN, the Food Allergy & Anaphylaxis Network that had been working on food allergy labeling for 20 years]. In contrast, ACTF [American Celiac Task Force, which later became the American Celiac Disease Alliance], which was composed of leaders of national Celiac Disease support groups, medical professionals, research institutions, and representatives of gluten-free food manufacturers, represented individuals with Celiac Disease. ACTF acted as the voice of the celiac community during the push to pass the FALCPA. **It was formed in 2003 after the Celiac Disease prevalence study results were released by the University of Maryland Center for Celiac Research.** This study ‘opened the doors for people paying much more attention’ to Celiac Disease, according to ACTF Co-chair Andrea Levario... ‘This was a true grassroots effort,’ Levario says. ‘Within the span of 18 months, ACTF was created, it mounted a lobbying effort, and it witnessed the successful passage of the FALCPA. ACTF ‘has no money. This was all done strictly via word of mouth, via the Internet, via e-mail... We were a voice in all this, and it was strictly, totally grassroots, every step of the way, which is pretty phenomenal.’”³⁷⁵

“At least one of the three national celiac disease support groups, **the Celiac Sprue Association (CSA), supported the FALCPA but advocated for the further labeling of all gluten-containing source ingredients.** [CSA is now part of the National Celiac Association.³⁷⁶] A provision in a 2002 bill that called for the inclusion of all gluten-containing grains in an allergen labeling scheme was dropped as a part of compromises reached while the bill was in committee.”³⁷⁷

Unfortunately, the pleas of the Celiac Sprue Association and others -- that the FALCPA's original language remain which required that Gluten be labeled -- were ignored. Their thought

³⁷³ “Immune-mediated mechanisms that are not IgE-mediated (such as mechanisms associated with celiac disease and contact dermatitis), and mechanisms that are not immune-mediated (such as lactose intolerance) typically are not associated with anaphylaxis or other immediately life-threatening conditions.” Source: <https://www.fda.gov/media/157637/download>

³⁷⁴ <https://www.cspinet.org/new/200209201.html>

³⁷⁵ <https://www.jstor.org/stable/26660870> , Page 102, Footnote 217.

³⁷⁶ <https://nationalceliac.org/>

³⁷⁷ <https://www.jstor.org/stable/26660870> , Page 142, Footnote 434 and 435.

leadership and efforts at the time could not compete with the well-funded lobbying efforts of the food industry looking for any negotiated concessions (wins) to the FALCPA. In spite of the 1999 Codex Criteria,³⁷⁸ and in spite of the fact that Gluten disclosures were required on all food labels in the original FALCPA bills and their respective amendments, some critics in the food industry were able to exert their influence on FALCPA's final language as part of a grand bargain. According to Inside Washington's (Health Policy's) "FDA Week", September 27, 2002 (page 5),

"Substitute [bill] pulls mandatory Gluten declaration... This week the Senate Health Committee passed without objection a watered-down version of a bill that would require food processors to label the eight most common types of food allergens in plain English. **The substitute version, unlike the underlying bill... would not require the declaration of Gluten.**"³⁷⁹ (emphasis added)

According to Open Secrets, there were three unique organizations that registered to lobby on S.741: Food Allergen Labeling and Consumer Protection Act of 2004, including: the American Farm Bureau, the Center for Science in the Public Interest and the American Bakers Association (ABA).³⁸⁰ The ABA touts itself as the "voice of the baking industry since 1897"³⁸¹ for its 300+ members,³⁸² and according to Paul Abenante, ABA President & CEO,

"ABA is a voluntary trade association dedicated to representing the interests of the wholesale baking industry before the United States Congress, federal agencies, state legislatures, and international regulatory authorities. ABA tackles key issues facing the **grain-based foods industry** and initiates key reforms to make positive impacts on the industry. ABA represents approximately 80% of the wholesale bakeries in the U.S. as well as their suppliers...In effect, ABA provides a comprehensive resource to the baking industry that can address most, if not all, sectors of the **grain-based foods industry**, operations and activities."³⁸³ (posted on April 17, 2004) (emphasis added)

According to When Food Is Poison, "Senator Kennedy introduced sister bills to those introduced in the House and helped work out a compromise amendment that was critical to the enactment of the FALCPA."³⁸⁴ The subsequent compromise bill served as the basis of S. 741, the FALCPA.³⁸⁵

³⁷⁸ "The revised list of those foods and ingredients known to cause food allergies and intolerance and whose presence should always be declared was identified as the following: Cereals containing gluten (i.e. wheat, rye, barley, oats, spelt or their hybridized strains) and their products."

³⁷⁹ https://fd19a27e-adc0-4b2e-a80e-88598593a644.usrfiles.com/ugd/fd19a2_e352e90b251941a1a5482f10f835f7c8.pdf

³⁸⁰ <https://www.opensecrets.org/Lobby/billsum.php?id=s741-108>

³⁸¹ <https://vimeo.com/455675294>

³⁸² <https://americanbakers.org/membership/member-list>

³⁸³

<https://web.archive.org/web/20040417021001/http://www.americanbakers.org/about/president.htm>

³⁸⁴ <https://www.jstor.org/stable/26660870> , page 110

³⁸⁵ <https://www.congress.gov/bill/108th-congress/senate-bill/741/all-info>

It is instructive to review FALCPA's Findings in Section 2, which expressly references Celiac Disease and the "recommended treatment is avoidance of glutens in foods" just like "a food allergic consumer must avoid the food to which the consumer is allergic."

D. FALCPA's Findings

"Section 202. Findings.

Congress finds that--

- (1) it is estimated that—
 - (A) approximately 2 percent of adults and about 5 percent of infants and young children in the United States suffer from food allergies; and
 - (B) each year, roughly 30,000 individuals require emergency room treatment and 150 individuals die because of allergic reactions to food;
- (2) **(A) eight major foods or food groups -- milk, eggs, fish, Crustacean shellfish, tree nuts, peanuts, wheat, and soybeans -- account for 90 percent of food allergies;**
(B) at present, there is no cure for food allergies; and
(C) a food allergic consumer must avoid the food to which the consumer is allergic;...
- (6) **(A) celiac disease is an immune-mediated disease that causes damage to the gastrointestinal tract, central nervous system, and other organs;**
(B) the current recommended treatment is avoidance of glutens in foods that are associated with celiac disease; and
(C) a multicenter, multiyear study estimated that the prevalence of celiac disease in the United States is 0.5 to 1 percent of the general population."³⁸⁶ (emphasis added)

Unlike the mandatory FALCPA labeling scheme for the Big 8 food allergens in the U.S., Gluten labeling is permissive (voluntary), in the U.S.

In other words, the information strongly suggests that the Celiac community took one for the proverbial team -- the food allergy community -- when the language for the labeling of Gluten was revised from mandatory to voluntary in order to get the FALCPA passed which required labeling of the Big 8 food allergens. This suggests a generosity of spirit by the Celiac community that in addition to the voluntary labeling of Gluten, the Celiac community's consumer protection needs would be addressed down the road with mandatory labeling of Gluten as a Major Food Allergen. Moreover, there had been efforts made by Celiac Journey to have the Food Allergy Research & Education ("FARE") and other organizations open their umbrella wider to embrace Gluten as a food allergen, but to date they have not really done so since their focus appears to have been exclusively on IgE-Mediated food allergies that have the potential to be immediately life-threatening.

In addition to Senator Jeff Sessions (R, Alabama) sponsoring S.741,³⁸⁷ there was broad bipartisan support for the FALCPA in the Senate with a total of 21 Co-Sponsors (10 Democrats and 11 Republicans) including: Senators Wayne Allard (R, Colorado), Jeff Bingaman (D, New Mexico), Susan Collins (R, Maine), Larry Craig (R, Idaho), Mike Crapo (R, Idaho), John Ensign

³⁸⁶ <https://www.fda.gov/media/77570/download>

³⁸⁷ <https://projects.propublica.org/represent/bills/108/s741>

(R, Nevada), Judd Gregg (R, New Hampshire), Tom Harkin (D, Iowa), Blanche Lincoln (D, Arkansas), Zell Miller (D, Georgia), Richard Shelby (R, Alabama), Pete Domenici (R, New Mexico), Mike Enzi (R, Wyoming), Gordon Smith (R, Oregon), Patty Murray (D, Washington), Orrin Hatch (R, Utah), Mary Landrieu (D, Louisiana), Ron Wyden, D, Oregon), Mark Pryor (D, Arizona), Dick Durbin (D, Illinois), and Maria Cantwell (D, Washington).

Food allergies and Celiac Disease are bipartisan issues since these health issues impact all Americans from every state, from every political party, from every political ideology, etc.

E. The Watered Down FALCPA & The Resulting Impact on 3.3 Million Americans with Celiac Disease, Plus Their Parents, Caretakers and Loved Ones

Since January 1, 2006, FALCPA has *required* that the top 8 Major Food Allergens must be labeled on all food products in the U.S. While there are critics about how FALCPA “fell short of true protection of food allergy sufferers,” this was nonetheless a watershed moment for the IgE-Mediated food allergy community.³⁸⁸

However, the Celiac community continued to experience gut-wrenching pain by having to wait a full decade for any type of *voluntary* FALCPA labeling protections to be enacted. It is instructive to understand how FALCPA fell short in so many ways in protecting the Celiac community. According to “When Food Is Poison: The History, Consequences, and Limitations of the Food Allergen Labeling and Consumer Protection Act of 2004”:

“The FALCPA contains a number of provisions designed to address food allergen safety concerns not met by the labeling requirements and to improve scientific, medical, and public knowledge about food allergies. The FALCPA directs that within two years after its enactment, the Secretary [of Health and Human Services] must issue a proposed rule to define and permit voluntary use of the term ‘gluten-free’ on food labels. The FALCPA

³⁸⁸ “Despite this important step forward, FALCPA left unregulated the use precautionary statements that warn consumers about the possibility of allergen contamination.⁴ This failure has left a back door wide open for makers of foods mark their products with blanket warnings of the potential presence of allergens, regardless of whether they pose an actual risk to consumers. This action may then preclude potential tort liability from consumers who suffer allergic reactions the items, and disables the Food and Drug Administration (FDA) from declaring the products misbranded or adulterated.⁵ Food manufacturers thus have a great incentive to use these warnings rather than to monitor products that do not specifically include one of the eight major allergens as an ingredient. Simultaneously, food allergic consumers may waive any right to litigate allergic reactions if they consume foods bearing precautionary warnings. FALCPA also falls short because it only regulates packaged food, and fails to regulate allergen labeling in restaurants.⁶ Restaurants present danger to food allergy sufferers because they lack uniform methods for informing customers of the contents of food and the possibility of allergen contamination. These consumers are instead left to rely on the assurances of wait staff and indirect communication with kitchen workers and chefs.” Source: Roses, Jonathan B. “Food allergen law and the Food Allergen Labeling and Consumer Protection Act of 2004: falling short of true protection for food allergy sufferers.” *Food and drug law journal* vol. 66,2 (2011): 225-42, ii. <https://www.jstor.org/stable/26661195> .

Also see Boyd, Marie C., “Serving Up Allergy Labeling: Mitigating Food Allergen Risks in Restaurants.” *Oregon law review* 97 (2018): 109, https://scholarcommons.sc.edu/cgi/viewcontent.cgi?article=2203&context=law_facpub

directs FDA to issue a final rule by August 2008. The House Committee Report (H.R. Rep. No. 108-608³⁸⁹ at 18) on the FALCPA states that, **‘[g]iven the devastating nature of Celiac Disease, the Committee urges the Secretary to move expeditiously in implementing the requirements of this section.’** Currently, there is no standard definition of ‘Gluten Free’ in the United States and studies have found that some products proclaiming themselves ‘Gluten Free’ may contain Gluten. The FALCPA calls for the Secretary to consult with experts and stakeholders when drafting the rule.”³⁹⁰ (emphasis added; page 119)

“While this provision to define ‘Gluten Free’ is a significant step in the right direction, use of this declaration by manufacturers merely is voluntary rather than mandatory. Although people with Celiac Disease will be able to trust ‘Gluten Free’ declarations beginning in 2008 [which did not occur until 2014], **the degree to which safety and convenience will improve for those with Celiac Disease depends on how widespread voluntary usage of the Gluten Free claim becomes. Earlier legislative allergen labeling efforts included provisions requiring the Secretary of HHS to assess, after a ‘Gluten Free’ standard is defined, whether additional labeling of Gluten is necessary on the label.** [‘Bills introduced in the 107th Congress, in addition to requiring the promulgation of a standard for ‘gluten-free,’ called for the Secretary of HHS to assess ‘whether additional requirements for the labeling of gluten are warranted and necessary to better inform individuals with celiac disease, and if other labeling is warranted and necessary, identify] the types of such labeling.’ S. 3001³⁹¹ and H.R. 5747³⁹², 107th Cong. Section 6(d) (2d Sess. 2002); see also S. 2499³⁹³, 107th Cong. Section 6(d) (2d Sess. 2002); S. Rep. No. 107-322³⁹⁴, at 8 (accompanying S. 2499³⁹⁵, as reported in Senate). (‘The committee also expects the Institute of Medicine report to inform a report by the

³⁸⁹ Rep. Barton, Joe. “Minor Use And Minor Species Animal Health Act Of 2004; Food Allergen Labeling And Consumer Protection Act Of 2004.” House of Representatives, 108th Congress, 2nd Session, Report 108-608, 15 July 2004. chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://www.congress.gov/108/crpt/hrpt608/CRPT-108hrpt608.pdf . Accessed 13 May 2022.

³⁹⁰ Derr, Laura E. “When Food Is Poison: The History, Consequences, and Limitations of the Food Allergen Labeling and Consumer Protection Act of 2004.” Food and Drug Law Journal, vol. 61, no. 1, 2006, pp. 65–165, <http://www.jstor.org/stable/26660870> . Accessed 13 May 2022.

³⁹¹ Sen. Kennedy, Edward M. [D-MA]. “S.3001 - Food Allergen Labeling and Consumer Protection Act.” 107th Congress (2001-2002.) <https://www.congress.gov/bill/107th-congress/senate-bill/3001> . Accessed 13 May 2022.

³⁹² Rep. Lowey, Nita M. [D-NY-18]. “H.R.5747 - Food Allergen Labeling and Consumer Protection Act.” 107th Congress (2001-2002.) <https://www.congress.gov/bill/107th-congress/house-bill/5747?s=1&r=21> . Accessed 13 May 2022.

³⁹³ Sen. Kennedy, Edward M. [D-MA]. “S.2499 - Food Allergen Labeling and Consumer Protection Act.” 107th Congress (2001-2002.) <https://www.congress.gov/bill/107th-congress/senate-bill/2499/summary/00> . Accessed 13 May 2022.

³⁹⁴ Sen. Kennedy, Edward M. “Food Allergen Labeling And Consumer Protection Act.” Senate, 107th Congress, 2nd Session, Report 1-7-322, 17 October 2002. chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://www.congress.gov/107/crpt/srpt322/CRPT-107srpt322.pdf . Accessed 13 May 2022.

³⁹⁵ Sen. Kennedy, Edward M. [D-MA]. “S.2499 - Food Allergen Labeling and Consumer Protection Act.” 107th Congress (2001-2002.) <https://www.congress.gov/bill/107th-congress/senate-bill/2499/summary/00> Accessed 13 May 2022.

Secretary to Congress on whether additional requirements for the labeling of gluten in food associated with celiac disease are warranted and necessary to better inform individuals with celiac disease. If the Secretary finds that other labeling of gluten in food associated with celiac disease is warranted and necessary, the report is to identify the types of such labeling and should describe why the different types of labeling are warranted and necessary.’) **This provision was cut from the FALCPA.**”³⁹⁶ (page 144) (emphasis added)

“The clear labeling of wheat under the FALCPA, in fact, may have the perverse effect of harming those who must avoid Gluten. A Gluten Free product always is wheat-free, but the reverse is not true. Children or caregivers of children with Celiac Disease may assume incorrectly that a wheat-free product is Gluten Free if they are not familiar with or do not remember the various terms for gluten-containing ingredients (e.g., rye, barley, and malt) besides wheat... It is clear, however, that including Gluten Containing Grains besides wheat in the FALCPA’s allergen labeling scheme, expressly requiring FDA to consider Celiac Disease in its ingredient exemption decisions and requiring the ‘Gluten Free’ declaration on products without Gluten could have gone significantly further to assist people living with this [Celiac] Disease.”³⁹⁷ (pages 143-145) (emphasis added)

It is no wonder that in explaining how Celiac Disease impacts their everyday life, the Celiac Disease Foundation has found that “75% of people find it difficult to explain their dietary needs to others.”³⁹⁸

The information suggests that the voluntary labeling scheme of Gluten Free food has been conflated with the voluntary adoption of a GF diet. The information further suggests that a voluntary Gluten Free diet gets conflated with Celiac Disease, a Non-IgE-Mediated food allergy. In turn, since Gluten is not required to be labeled as a Major Food Allergen, that has adversely impacted the Celiac community over time in terms of obfuscating our community’s medical needs and the seriousness with which others perceive the medically required Gluten Free diet.

Our research suggests that the medical requirement for a strict Gluten Free diet coupled with the voluntary labeling of Gluten under FALCPA have converged to provide “medical legitimacy” to those who choose to eat Gluten Free. Conversely, to those with Celiac, the voluntary labeling of Gluten and not referring to a Celiac as a food allergy and Gluten as a food allergen, has led to undermining the medical legitimacy of the only treatment available for Celiac – a strict Gluten Free diet. That said, Gluten appears to be uniquely positioned among the potentially life-threatening food allergens, as the only one which has been widely adopted as a lifestyle choice by those who do not medically require avoiding Gluten in their diets.

³⁹⁶ Derr, Laura E. “When Food Is Poison: The History, Consequences, and Limitations of the Food Allergen Labeling and Consumer Protection Act of 2004.” Food and Drug Law Journal, vol. 61, no. 1, 2006, pp. 65–165, <http://www.jstor.org/stable/26660870> . Accessed 13 May 2022.

³⁹⁷ Derr, Laura E. “When Food Is Poison: The History, Consequences, and Limitations of the Food Allergen Labeling and Consumer Protection Act of 2004.” Food and Drug Law Journal, vol. 61, no. 1, 2006, pp. 65–165, <http://www.jstor.org/stable/26660870> . Accessed 13 May 2022.

³⁹⁸ <https://www.facebook.com/photo?fbid=418649703637203&set=a.366572858844888>

VIII. “Contact with Manufacturer” & “Ask Questions About Ingredients and Preparation When Eating at Restaurants” - Real World Examples

“We are moms and busy. We don’t have time to be at the grocery stores, going on Web sites for all the things we need.”

– Mother of an allergic child, with income <\$25K”³⁹⁹

“What is food for one is poison for another.”

U.S. Senator Royal S. Copeland, MD (D, NY, 1923-1938)⁴⁰⁰

A. Overview

According to the FDA, “If you have any doubts about a product’s ingredients and whether or not the product is gluten-free, the FDA recommends that you should contact the manufacturer or check its website for more information.”⁴⁰¹ The FDA also advises that “consumers who are allergic to particular foods to ask questions about ingredients and preparation when eating at restaurants or any place outside the consumers home.”⁴⁰²

It is instructive to view research published in the Academy of Management, “The Effects of Mandatory and Voluntary Regulatory Pressures on Firms Environmental Strategies: A Review and Recommendations for Future Research.”

“This article presents an in-depth review of scholarship on how mandatory and voluntary regulatory pressures on firms affect their environmental strategies and performance. Although mandatory regulation typically has a strong and positive influence on firms’ environmental performance, studies of the effects of voluntary pressures demonstrate that by themselves they are unlikely to bring about significant improvement in environmental outcomes.”⁴⁰³

From this analogy, one can glean how these same findings arguably apply with respect to mandatory vs. voluntary labeling of potentially life-threatening food allergens by the food industry.

“Nearly all the literature works we have reviewed confirm that the mandatory powers of government are the most effective lever that society has to alter firm environmental strategies and performance. However, potential negative implications on competitiveness have generated a mixed and relevant debate. In this review, we have shown that voluntary

³⁹⁹ <https://www.foodallergy.org/media/1059/download>

⁴⁰⁰ Hearing Before the Senate Comm. on Commerce, 73d Cong. (1934), reprinted in Charles Wesley Dunn, Federal Food, Drug, and Cosmetic Act: A Statement of Its Legislative Record 1176 (1987).], at 1176.

⁴⁰¹ <https://www.fda.gov/consumers/consumer-updates/gluten-free-means-what-it-says>

⁴⁰² <https://www.fda.gov/food/food-allergensgluten-free-guidance-documents-regulatory-information/food-allergen-labeling-and-consumer-protection-act-2004-questions-and-answers#>

⁴⁰³ <https://carlsonschool.umn.edu/sites/carlsonschool.umn.edu/files/2020-01/annals.2018.0014.pdf>

programs have arisen to supplement mandatory regulation; however, research has found that often the results of these programs are disappointing.”⁴⁰⁴

Here are just a few illustrative, but not exhaustive, anecdotal examples of how contacting the manufacturer or checking the Web site for more information can lead a consumer in circles and not provide any clarifying details. We can attest to the time consuming nature and frustration associated with reaching out to food manufacturers. Moreover, these examples below illustrate that in the absence of mandatory labeling schemes, many companies revert to doing the minimum. In other words, they revert to doing only what is legally required and that leaves consumers vulnerable to dangerous ingestion of potentially life-threatening food allergens, in this case Gluten.

B. Example A - Wells Manufacturing

Following is an email exchange between Leslie Bari and Halo Top Consumer Response on May 2, 2022:

From: Halo Top Consumer Response <ConsumerResponse@halotopcreamery.com>

Date: Mon, May 2, 2022 at 2:31 PM

Subject: Halo Top Consumer Response Ticket #865550

To: <leslie@theconstitutional.com>

“Thank you for contacting Halo Top Consumer Response. We appreciate hearing from our valued consumers. Wells Enterprises, Inc. (“Wells”), manufacturer of ice cream and frozen novelty products, **follows all federal laws and regulations** and is committed to supplying the highest quality and safest ice cream and frozen novelty products to its consumers. **While many of our branded ice creams and frozen novelty products are free of gluten, Wells does not presently validate or certify that our products are “gluten-free” and, consequently, we do not label our (Wells) branded products as such. We provide all required nutritional information on the nutrition facts panel and ingredient label on each package to assist consumers in purchasing products that meet their dietary and lifestyle needs.** Or you may call us at 1-800-331-0830 and ask about your favorite flavors. If I can be of additional assistance, feel free to contact me. -- Julie, Consumer Response Representative”⁴⁰⁵ (emphasis added)

C. Example B - Dreyer’s Ice Cream

Following is an FAQ on Dreyer’s Grand Ice Cream as visited on May 2, 2022:

“Is Dreyer’s Ice Cream Gluten Free?

As a general rule, the gluten in Dreyer’s frozen dessert products is present only in the added bakery products, such as cookies, cake or brownies. We always label the eight major food allergens on our package by their common name. We recommend to always check the label for the most current information before purchasing and/or

⁴⁰⁴ Academy of Management Annals 2020, Vol. 14, No. 1, 339365.
<https://doi.org/10.5465/annals.2018.0014>

⁴⁰⁵ Email from Halo Top Consumer Response to Leslie Bari, May 2, 2002.

consuming a product. The exception to this rule is our Slow Churned French Silk ice cream, which contains gluten in the natural flavors.”⁴⁰⁶ (emphasis added)

D. Example C – Gatorade

PepsiCo⁴⁰⁷ presents a tale of different food allergens: the Top 8 Major Food Allergens vs. Gluten.

The Top 8:

“Question: If I have food allergies, how will I know which of your beverages I can safely drink?

Answer: If one of our products contains milk, eggs, peanuts, tree nuts, fish, crustacean shellfish, wheat or soy, it is identified on the product’s label. You can also check for these eight common allergens in the Allergen Lookup chart below.”⁴⁰⁸

“Question: What is special about the eight categories of allergens you list on your products?

Answer: The U.S. Food & Drug Administration identifies these eight categories of allergens - milk, eggs, peanuts, tree nuts, fish, crustacean shellfish, wheat and soy in its Food Allergen Labeling and Consumer Protection Act. The eight categories of allergens account for over 90 percent of all documented food allergies in the U.S. and represent the foods most likely to result in severe or life-threatening reactions.”⁴⁰⁹

Gluten:

“Question: Does Gatorade contain gluten?

Answer: Gluten is typically found in certain grains such as wheat, barley and rye. None of the ingredients in Gatorade ready-to-drink, Gatorade mix (bulk and sticks), G2 products, Recover Protein Shakes, Recover Protein Powders, Prime Energy Chews, and Gatorade Endurance products are derived from grains or flours that have been linked to gluten sensitivity. While these products are not formulated using gluten-containing ingredients, they have NOT been tested to be gluten-free. There is a possibility the ingredients were exposed to/stored next to gluten-containing foods during processing.”⁴¹⁰

⁴⁰⁶<https://www.icecream.com/us/en/brands/dreyers/faq#:~:text=Is%20Dreyer's%20Ice%20Cream%20Gluten,package%20by%20their%20common%20name.>

⁴⁰⁷ “PepsiCo products are enjoyed by consumers more than one billion times a day in more than 200 countries and territories around the world. PepsiCo generated \$79 billion in net revenue in 2021, driven by a complementary beverage and convenient foods portfolio that includes Lay's, Doritos, Cheetos, Gatorade, Pepsi-Cola, Mountain Dew, Quaker, and SodaStream. PepsiCo's product portfolio includes a wide range of enjoyable foods and beverages, including many iconic brands that generate more than \$1 billion each in estimated annual retail sales.” Source:

<https://www.pepsico.com/who-we-are/about-pepsico>

⁴⁰⁸ <https://www.pepsicobeveragefacts.com/home/allergens>

⁴⁰⁹ <https://www.pepsicobeveragefacts.com/home/allergens>

⁴¹⁰ <https://contact.pepsico.com/gatorade/article/does-gatorade-contain-gluten?>

This doubletalk from PepsiCo is nonsense. However, this is an anecdotal example of living with Celiac in terms of trying to determine whether food products have Gluten in them because of FALCPA's voluntary labeling scheme.

We as a community have the right to know whether food products like Gatorade have Gluten in them, just like the top 9 Major Food Allergens. If Gluten was required to be labeled, the response would have been, "If one of our products contains Gluten, it is identified on the product's label."

Anecdotally, I have heard many soccer sideline discussions and participated in numerous online discussions among parents and caretakers of kids with Celiac about Gatorade when we try to understand whether Gatorade is safe to consume. Curiously, as per our personal experience in Italy in August 2022, Gatorade in Italy is clearly marked "SENZA GLUTINE" (Gluten Free).⁴¹¹

E. Example D – Frozen Peas: Are These Celiac Safe?

On January 22, 2022, a member of a Celiac Facebook group posted the following question, "Hi! Does anyone know if Aldi's Simply Nature brand frozen peas⁴¹² (or generally frozen fruits and veggies) are celiac safe?"⁴¹³ The 16 comments from the support group offered various opinions about the safety of this product given the absence of labeling information about Gluten.

According to the Celiac Disease Foundation,

"Fresh and frozen fruits and vegetables are naturally gluten-free. **However, it is important to read labels on any processed fruits and veggies,** as well as dried fruit and pre-prepared smoothies. Additionally, packaged frozen potatoes are not always gluten-free, and labels should be read carefully when considering these products."⁴¹⁴

This is an anecdotal example of how conditioned consumers are to be on alert and need to buy premium priced foods since there are so many unknown Gluten containing ingredients potentially lurking in the voluntary labeling scheme.

F. Example E – M&Ms Milk Chocolate

The Gluten guessing game goes on every day in the absence of mandatory labeling of Gluten as a Major Food Allergen. The efforts made and anxiety endured by parents and caretakers is palpable. Social media groups are replete with the Celiac community trying to decipher lots of confusing consumer information, and it is not just limited to Halloween or other candy-oriented holidays. One Celiac mom posted about M&Ms, "I do not understand how so much conflicting information is out there. Every time I reach out to Mars, call or email, this is the inconsistent information I get." Hm&m. Here are some examples:

January 4, 2021

"Thank you for contacting Mars Wrigley. We appreciate your interest in M&M'S® Milk Chocolate. **Although our M&M'S® Milk Chocolate do not contain gluten,** we do not

⁴¹¹ Author's personal shopping experience in Rome, Italy, August 2022.

⁴¹² <https://www.aldi.us/en/products/frozen-foods/frozen-fruit-vegetables/detail/ps/p/simply-nature-organic-peas-or-corn/>

⁴¹³ <https://www.facebook.com/photo/?fbid=10227561920775964&set=gm.10158038672492245>

⁴¹⁴ <https://celiac.org/gluten-free-living/gluten-free-foods/>

have a gluten free statement on our packaging because this product is made in a facility where other products that do contain gluten are manufactured. We understand that people with food allergies have to be careful with the food they eat. Moving forward please feel free to check the back of the package for allergen information.”⁴¹⁵ (emphasis added)

March 16, 2022

“Hello Kelly... **Any ingredient which contains gluten, such as wheat, barley, rye, and oats, is listed on the ingredients list on the pack.**

In areas where gluten may be present, we always provide a statement (i.e. May contain wheat, etc.). There are really strict controls in our factories surrounding gluten and other allergens. We make sure that sufficient cleaning structures are in place to avoid any cross-contamination.

Although the product does not contain gluten, we do not have a gluten-free statement on our packaging because this product is made in a facility where other products that do contain gluten are also manufactured.

At this time, we do not have a list of gluten free products for chocolate. All our chocolate products either have gluten or could be made on machinery that does. We hope that this information has been helpful.”⁴¹⁶ (emphasis added)

October 28, 2022

“Thank you for contacting us about M&M’S. **We do not label our Chocolate products as gluten-free.** This is because all our Chocolate products either have gluten, are made on machinery that also makes products containing gluten, or is made in a facility that uses gluten in other products. **Whether or not the product includes a ‘may contain’ statement, it is never labeled as gluten-free because we cannot guarantee that it is gluten-free despite the cleaning and other protocols that we use at our sites.** We hope this information has been helpful. If you have further questions or concerns, please don’t hesitate to reach out to us.”⁴¹⁷ (emphasis added)

In Fall 2022, President Biden gave my 9 year old son Jax a couple of boxes of his POTUS M&Ms! Jax was so excited when he showed us the M&Ms in their special box featuring the “Seal of the President of the United States” and President Biden's signature! So cool, right? For most kids, they would have ripped the box open and gobbled up the M&Ms on the spot. Well, not so fast for those kids like Jax in the Celiac world with a potentially life-threatening food allergy to Gluten.

My wife and I quickly saw Jax's smile vanish when the fear and uncertainty with the potential for danger once again arose with the voluntary labeling of Gluten in the U.S., including on the POTUS M&Ms. “Does this product have Gluten in it?” has been the daily refrain in our lives ever since Jax was diagnosed in 2018 with Celiac Disease. For more information, see “POTUS M&M’s Epitomize Need to Label Gluten as a Major Food Allergen to Eliminate Fear & Danger.”⁴¹⁸

⁴¹⁵ Response to Michele H. from Mars Wrigley, 1/4/21 (on file with author)

⁴¹⁶ Mars Wrigley North America Email to Kelly P. From Chris, Mars Customer Care, 3/16/22, ref:00D0Y34dhp._5008d480m3:ref (on file with author)

⁴¹⁷ Email to Jon Bari from Jaja, Mars Customer Care, Case ID: 03036440,10/28/22 (on file with author)

⁴¹⁸ www.celiacjourney.com/mms

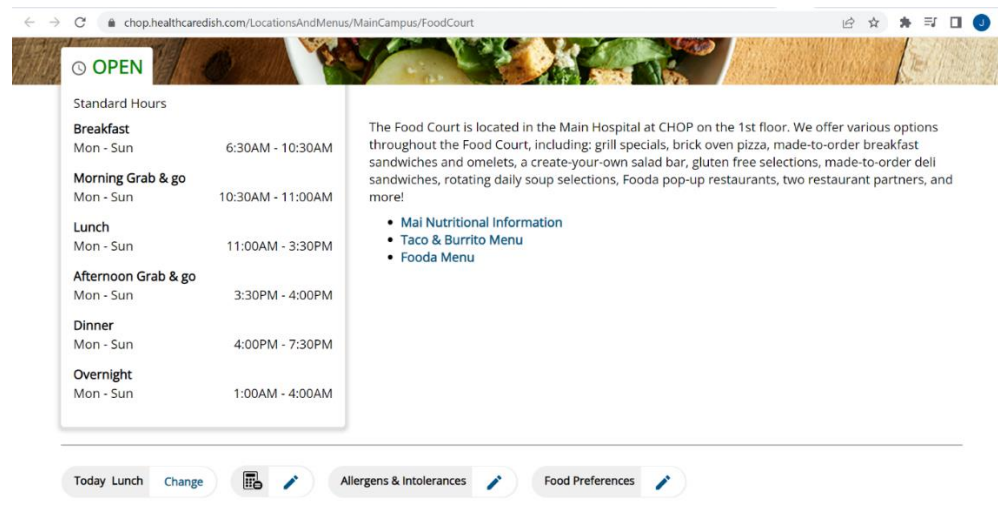
G. Example F – ARAMARK & Children’s Hospital of Philadelphia’s (CHOP) Food Court

As discussed, our son Jax has been treated for Celiac Disease at Children’s Hospital of Philadelphia (“CHOP”). When I viewed the online menu filtering at CHOP’s Food Court (see screen shots below), it revealed a blind spot to serving Celiac safe Gluten Free food to meet the medical needs CHOP’s patients, staff and visitors who cannot eat Gluten. For example, I was shocked when I saw that Gluten was not even listed as an Allergen or Intolerance. Instead “Made without Gluten” was listed as a “Food Preference” along with Vegan and Vegetarian options.⁴¹⁹ How could one of the world’s leading pediatric treatment and research hospitals allow this? How could Aramark, one of the world’s leading managed outsourced food services companies⁴²⁰ which CHOP contracts with to operate the CHOP Food Court, allow this?

My child’s medically required need for Gluten Free food is not a food preference in any way! However, that is one example of society’s bias with viewing the medically required Gluten Free needs of the Celiac community as less serious than the medical needs of the typical IgE-Mediated food allergy.

When one does filter out for both Wheat as an allergy and intolerance, and Gluten Free as a “food preference,” one sees that there are no real choices left on the menu for those who medically require a strict Gluten Free diet.

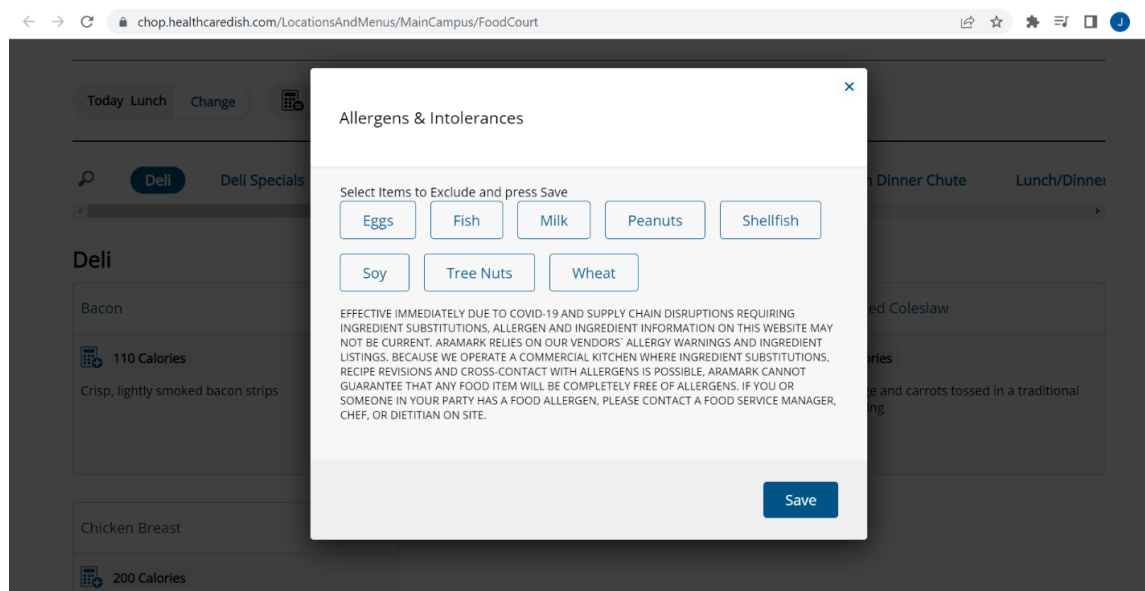
CHOP Food Court, Main Hospital, Web Site, Landing Page



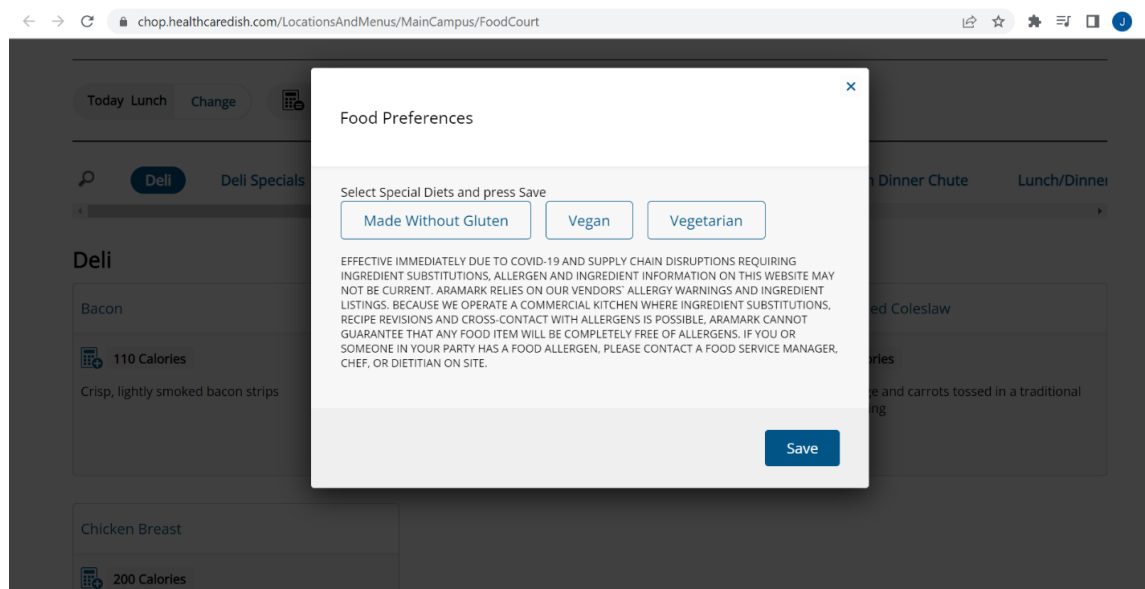
⁴¹⁹ <https://chop.healthcaredish.com/LocationsAndMenus/MainCampus/FoodCourt>

⁴²⁰ “Aramark (NYSE: ARMK) proudly serves the world’s leading educational institutions, Fortune 500 companies, world champion sports teams, prominent healthcare providers, iconic destinations and cultural attractions, and numerous municipalities in 19 countries around the world with food, facilities, and uniform services. Because our culture is rooted in service, our employees strive to do great things for each other, our partners, our communities, and our planet. Aramark ranked No. 1 In the Diversified Outsourcing Services Category on FORTUNE’s 2022 List of Worlds Most Admired Companies and has been named to DiversityInc’s Top 50 Companies for Diversity list, the Forbes list of Americas Best Employers for Diversity, the HRC’s Best Places to Work for LGBTQ Equality and scored 100% on the Disability Equality Index.” And <https://www.aramark.com/content/dam/aramark/en/about/newsroom/Aramark%20Capabilities%20-%20Apr%202022.pdf>

CHOP Food Court, Main Hospital, Web Site, “Allergens & Intolerances” Selected



CHOP Food Court, Main Hospital, Web Site, “Food Preferences” Selected



The bottom line is that in the absence of mandatory labeling schemes, Aramark and CHOP revert to doing the minimum. In other words, they revert to doing only what is legally required and that leaves consumers (patients at Children’s Hospital) vulnerable to dangerous ingestion of potentially life-threatening food allergens, in this case Gluten.

IX. FDA's Draft Guidance Illustrates Bias Against Celiac Disease

"Injustice anywhere is a threat to justice everywhere.

**We are caught in an inescapable network of mutuality, tied in a single garment of destiny.
Whatever affects one directly, affects all indirectly."**

-- Dr. Martin Luther King, Jr.

A. An Inequitable Decision-Making Framework – Suspect Classification

The FDA's Draft Guidance serves as an illustrative example of the Federal government not providing consistent and systematic fair, just, and impartial treatment of Celiacs who belong to an underserved community and who have been historically denied such treatment.

The FDA's Draft Guidance presents an inequitable evaluation framework, as well as perpetuates flawed and ingrained scientific, governmental and societal biases including:

1. A Gluten Free diet is all that is needed to treat Celiac Disease, as opposed to all that has ever been historically available to treat Celiac Disease.
2. With respect to labeling food products in the United States, the voluntary Gluten Free labeling scheme⁴²¹ sufficiently protects consumers who are on medically required and very restrictive Gluten Free diets, as opposed to all that has ever been historically utilized labeling-wise.
3. Othering the consumer protection needs for Celiacs in the United States with not evaluating the public health importance of Gluten as a food allergen because this Non-IgE-Mediated food allergy is not capable of triggering anaphylaxis and being *immediately* life-threatening, while seemingly ignoring that Celiacs face potentially life-threatening and severe adverse health effects⁴²² that can arise through Gluten ingestion, including by way of example and not limitation: anemia, cancer, heart disease, immunological scarring, intestinal damage, malnutrition, etc.⁴²³

On November 13, 2021, January 13, 2021, and November 9, 2022, the U.S. Department of Health and Human Services posted the following to Instagram and Facebook, "**Going gluten-free? It's easier than ever. #GlutenFreeAwarenessMonth**"⁴²⁴ The post does not expressly mention Celiac Disease, and moreover the messaging asks a question ("Going gluten-free?") and suggests that the post is targeted towards those who are voluntarily considering the adoption of a

⁴²¹ The FDA's final rule defining Gluten Free for food labeling became effective on September 4, 2013, and August 5, 2014 was the date when FDA-regulated foods labeled Gluten Free must comply with all requirements established by the final rule.

<https://www.federalregister.gov/documents/2013/08/05/2013-18813/food-labeling-gluten-free-labeling-of-foods> , and

<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/small-entity-compliance-guide-gluten-free-labeling-foods#>

⁴²² <https://www.fda.gov/consumers/consumer-updates/gluten-free-means-what-it-says>

⁴²³ FDA Comment ID: FDA-2021-N-0553-1169, FDA Tracking Number: l6g-mawc-nbs8, August 5, 2022, https://downloads.regulations.gov/FDA-2021-N-0553-1169/attachment_1.pdf

⁴²⁴ The November 9, 2021 examples are for all intents and purposes the same, including with the same image and primary messaging, but with some differing language in the post's text.

<https://www.instagram.com/p/CkviWsrOFI2/> and

<https://www.facebook.com/HHS/posts/pfbid02TGK5MHZrht83F28UmwxbZNYfbmDwY3fbfZ9d8ycxyKN3GpDy8NtKhgkAREwSH5S5l>

gluten-free lifestyle. For those with Celiac, there is no question mark for a strict Gluten Free diet since it is the only treatment that has ever been historically available. To suggest that a Gluten Free diet is “easier than ever” trivializes the treatment burden for Celiac patients and parents. It is insensitive at best and at worst shows a deep disconnect from HHS to the unmet medical needs of the Celiac community and illustrates another example of how the Celiac community has been historically underserved by the Federal government. Ironically, the HHS social media posts link to a page on the NIH’s National Library of Medicine which states in part,

“On this [Gluten Free] diet, you need to learn which foods contain gluten and avoid them. **This is not easy, because gluten is in many foods and food products...** Because so many foods contain gluten, **this can be a hard diet to follow.** It can feel limiting when you shop or eat out.”⁴²⁵ (emphasis added)

A search of Facebook suggests that the last time that HHS posted anything on Facebook expressly about Celiac Disease was more than eight years ago on August 13, 2014.⁴²⁶

B. A Tale of Two Evaluation Frameworks Whereby FDA’s Draft Guidance is Inequitable and Biased

It is instructive to review the differences in the language between the following frameworks from the FDA and the FAO/WHO, even though the 2021 FAO/WHO Expert Consultation and the FAO and WHO 2022 Risk Assessment of Food Allergens was chaired by the FDA’s Dr. Lauren Jackson and included the FDA’s Dr. Luccioli. Specifically, it is instructive to review how the FDA’s requirement for the evaluation of the public health importance of labeling food allergens other than the Major Food Allergens is a function of the food allergen being capable of triggering anaphylaxis through an IgE-Mediated mechanism. The FDA’s requirement is arbitrary, exclusionary, outdated and dangerous.

Document	FDA’s “Evaluating the Public Health Importance of Food Allergens Other Than the Major Food Allergens Listed in the Federal Food, Drug, and Cosmetic Act: Guidance for FDA Staff and Stakeholders – Draft Guidance”, Docket: FDA-2021-N-0553, April 19, 2022	<u>“FAO and WHO 2022 Risk Assessment of Food Allergens. Part 1 - Review and validation of Codex Alimentarius Priority Allergen List Through Risk Assessment. Meeting Report. Food Safety and Quality Series No. 14, Rome.”</u> Chaired by the FDA’s Dr. Lauren Jackson
Language	“As discussed in section III.A, <u>this document addresses the food allergies that have been most studied and understood clinically i.e., -- IgE-mediated food allergies.</u> Therefore, the initial question for us to address when we evaluate the public health	“The Expert Committee identified that food hypersensitivity disease consideration for the established criteria would primarily be given to IgE-mediated food allergies and coeliac disease⁴²⁸ [Non IgE-Mediated] since these diseases are well documented to cause serious

⁴²⁵ <https://medlineplus.gov/ency/patientinstructions/000813.htm?linkId=100000161686901>

⁴²⁶ <https://www.facebook.com/HHS/photos/a.577318915631772/803728956324099>

⁴²⁸ “Coeliac” is the Greek spelling of Celiac which is used in some parts of the world.

	<p>importance of a food or component of food as a food allergen is whether there is robust evidence that an adverse reaction to the food or component of food is IgE-mediated (Factor #1)”⁴²⁷ (emphasis added)</p>	<p>adverse public health outcomes. While food allergen data in relation to other immune-mediated responses to food (e.g. eosinophilic gastroenteropathies, food protein-induced enterocolitis syndrome) exist and were also considered in the criteria assessment for prevalence (and severity), these data were not found to be sufficiently robust with regards to prevalence, potency or severity and thus were only secondary considerations. Non-immune-mediated diseases like lactose intolerance and fructose malabsorption were not considered by the Committee owing to lack of sufficient comparative food allergen data and lack of documented evidence that these diseases cause serious adverse public health outcomes (Figure 1).”⁴²⁹ (emphasis added)</p>
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In evaluating this Citizen Petition (and all comments submitted in response to the FDA’s Draft Guidance, including the Bari Comments), the FDA should seek guidance from the FDA’s Dr. Lauren Jackson, FDA’s Dr. Stefano Luccioli, the FDA’s Dr. Douglas Balentine along with Dr. Joseph Baumert, Dr. Stephen Taylor, and Dr. J. Emilio Esteban. These thought leaders served with other esteemed members of the 2021/2022 FAO/WHO Expert Consultation (chaired by Dr. Jackson) which included “scientists, regulators, physicians, clinicians, and risk managers from academia, government and the food industry”⁴³⁰ and together they published the FAO and WHO 2022 Risk Assessment of Food Allergens. Part 1 - Review and validation of Codex Alimentarius Priority Allergen List Through Risk Assessment.” In that 2022 FAO/WHO Expert Consultation, these experts relied on a different criteria (from the 2022 FDA’s Draft Guidance) for their systematic and thorough assessments to evaluate the prevalence, severity and potency of adverse health impacts of ingesting Gluten to those with Celiac Disease.

Dr. Jackson’s 2022/2021 FAO/WHO Expert Consultation stated:

“The Expert Committee determined that **only foods or ingredients that cause immune-mediated hypersensitivities such as IgE-mediated food allergies and coeliac [Celiac] disease should be included on the list of foods and ingredients included in section 4.2.1.4 of the GSLPF [General Standard for the Labelling of Prepacked Foods]**,”⁴³¹ and that the **GSLPF list includes Gluten.**

⁴²⁷ <https://www.fda.gov/media/157637/download> , page 38.

⁴²⁹ <https://www.fao.org/3/cb9070en/cb9070en.pdf> , page 7.

⁴³⁰ <https://www.fao.org/3/cb4653en/cb4653en.pdf>

⁴³¹ <http://www.fao.org/3/cb4653en/cb4653en.pdf>

“Based on systematic and thorough assessments which used all three criteria (prevalence, severity and potency), the Committee recommended that the following should be listed as priority allergens: Cereals containing gluten (i.e., wheat and other Triticum species, rye and other Secale species, barley and other Hordeum species and their hybridized strains), crustacea, eggs, fish, milk, peanuts, sesame, specific tree nuts (almond, cashew, hazelnut, pecan, pistachio and walnut).”^{432 433}
(emphasis added)

In other words, these worldwide experts (including 6 Americans and FDA officials) recognized the significance of the Non-IgE-Mediated immune response as equally important in terms of consumer protection to those who suffer from IgE-Mediated food allergy to the other seven of the “Big 8” including: crustacea, eggs, fish, milk, peanuts, sesame, specific tree nuts:

“Criteria for the addition of foodstuffs to the list of the Codex Committee on Food Labelling... Products of rye, barley and oats would not be required to meet the criteria set out in (i) and (ii) [for IgE-Mediated allergic reactions] above because IgE-mediated allergic reactions to these cereal grains are uncommon.”⁴³⁴

See Section IV. D. in this Citizen Petition, “2021 FAO/WHO Expert Consultation Label Gluten as Priority/Major Food Allergen Based on the Criteria of Prevalence, Severity & Potency.”

The FDA’s Draft Guidance also suggests an admission of the pernicious impact that the lack of Federal research funding for Celiac has had with regard to how the FDA assesses and implements consumer protection. In other words, since Celiac research (Non-IgE-Mediated food allergy) has historically been underfunded, including from the NIH and Department of Defense, Celiac is not as well studied (arguably one of the least studied food allergies) and understood clinically. Therefore, the FDA’s Draft Guidance suggests that Non-IgE-Mediated food allergies are not as important and do not deserve the same consumer protections with labeling as typical IgE-Mediated food allergies which are better funded and “have been the most studied and understood clinically.” The FDA’s Draft Guidance further suggests a classic negative feedback loop indicating how the Celiac community has been historically underserved by the Federal government, and moreover, how it will continue to be underserved based on being underserved in the past.

C. Scientific Factors in the FDA’s Draft Guidance Relevant to the Public Health Importance of a Non-Listed Food Allergen

The FDA’s Draft Guidance’s “Scientific Factors Relevant to the Public Health Importance of a Non-Listed Food Allergen” in Section IV (“Scientific Factors”) are biased and exclusionary. Therefore, the FDA’s Draft Guidance is inequitable to 3 million Americans with Celiac Disease,

⁴³² “Due to the lack of data on prevalence, severity and/or potency, or due to regional consumption of some foods, the Committee recommended that some of the allergens, ... oats, ... should not be listed as global priority allergens but [Oats] may be considered for inclusion on priority allergen lists in individual countries.” <http://www.fao.org/3/cb4653en/cb4653en.pdf>
While Oats are naturally Gluten Free, cross contamination with Gluten is for all intents and purposes inevitable. See Section IV.G. in this Citizen Petition entitled, “Oats Must Be Included by the FDA as a Gluten Containing Grain and Thus Declared on All Food Packages.”

⁴³³ <http://www.fao.org/3/cb4653en/cb4653en.pdf>

⁴³⁴ <https://www.fao.org/3/cb9070en/cb9070en.pdf> (pages 134-136)

their parents and caretakers, and an additional estimated 20+ million others who have Non-Celiac Gluten Sensitivity (“NCGS”)⁴³⁵, an IgE-Mediated allergy to Rye, Barley or Oats, or who are following a medically required Gluten Free diet.⁴³⁶

Moreover, the Scientific Factors perpetuate flawed scientific, societal and governmental biases: A Gluten Free diet is all that is needed to treat Celiac Disease, as opposed to all that has ever been historically available and with respect to labeling food products in the US, the voluntary Gluten Free labeling scheme is all that is needed when that is all that has ever been available in the US.

It is absolutely maddening that the FDA has othered the consumer protection needs of the Celiac community by lumping Celiac and lactose intolerance together, “Immune-mediated mechanisms that are not IgE-mediated (such as mechanisms associated with celiac disease and contact dermatitis), and mechanisms that are not immune-mediated (such as lactose intolerance) typically are not associated with anaphylaxis or other immediately life-threatening conditions.”⁴³⁷

By way of example, let’s examine the following from Section IV of the FDA’s Draft Guidance:

“We have identified the following scientific factors that we generally intend to consider when evaluating the public health importance of a food allergen in the United States:

- Factor #1: **evidence of IgE-mediated food allergy**
- Factor #2: **the prevalence of an IgE-mediated food allergy** in the U.S. population
- Factor #3: **the severity of IgE-mediated food allergic reactions**
- Factor #4: **the allergenic potency**

Our scientific factors are consistent with the 1999 Codex criteria (Ref. 25), the revised criteria recommended by the International Life Sciences Institute-Europe (ILSI-EU) (Ref. 26), published frameworks from ILSI-EU and public, private, and academic partners in Europe for the evaluation of public health importance of a food allergen (Ref. 26 and Ref. 27), publications from ILSI-EU and public, private, and academic partners in Europe that evaluate published frameworks (Ref. 28 and Ref. 29), and the National Academy of Sciences, Engineering and Medicine (NASEM) (Ref. 2; the NASEM report). See Appendix A for further discussion of these criteria and frameworks.”⁴³⁸ (emphasis added)

In truth and in fact, as previously detailed with respect to the 1999 Codex Criteria’s recommendation that the presence of cereals containing Gluten should always be declared on packaged food labels, the FDA’s Scientific Factors are **not consistent** with the 1999 Codex Criteria recommendations as detailed in the FDA’s Ref. 25 (1999 Codex Criteria). Period. Full stop.

⁴³⁵ <https://www.verywellhealth.com/how-many-people-have-gluten-sensitivity-562965>

⁴³⁶ According to the National Celiac Association, there is a demand for Gluten Free food from families with children with an Autism Spectrum Disorder. There are a number of other conditions, particularly gastric and autoimmune conditions, where a Gluten Free diet may diminish symptoms. See <https://nationalceliac.org/wp-content/uploads/2018/04/GF-Food-Assistance-GuideGeneralv3.pdf> , and <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7915454/>

⁴³⁷ <https://www.fda.gov/media/157637/download>

⁴³⁸ <https://www.fda.gov/media/157637/download>

According to the 1999 Codex Criteria,

“The revised list of those foods and ingredients known to cause food allergies and intolerance and **whose presence should always be declared** was identified as the following: **cereals containing gluten (i.e. wheat, rye, barley, oats, spelt or their hybridized strains) and their products**; Crustacea and products of these; Egg and egg products; Fish and fish products; Peanuts, soybeans, and products of these; Milk and milk products (lactose included); Tree nuts and nut products; and Sulfites in concentrations of 10 mg/kg or more.”⁴³⁹ (emphasis added)

Additionally, the 1999 Codex Criteria, “Criteria for the addition of foodstuffs to the list of the Codex Committee on Food Labelling,”

“In determining whether a foodstuff should be added to the list of common allergenic foods drawn up by the Codex Committee on Food Labelling, the Panel recommended that all of the following criteria be met:

- (i) The existence of a credible cause-and-effect relationship, based on a positive reaction to a double-blind placebo-controlled food challenge or unequivocal reports of a reaction with the typical features of a severe allergic or intolerance reaction.
- (ii) The existence of reports of systemic reactions after exposure to the foodstuff, the reactions including atopic dermatitis, urticaria, angio-oedema, laryngeal oedema, asthma, rhinitis, abdominal pain, diarrhoea, vomiting, anaphylactic shock and chronic severe malabsorption syndrome.
- (iii) Data on the prevalence of food allergies in children and adults, supported by appropriate clinical studies (i.e. double-blind placebo-controlled food challenges) in the general population of several countries. However, the Panel noted that such information is available only for infants, from certain countries and for certain foodstuffs. The Panel therefore agreed that any available data, such as the comparative prevalence of a specific food allergy in groups of patients in several countries, could be used as an alternative, preferably backed up by the results of a double-blind placebo-controlled food challenge.

The list adopted by the Codex Committee on Food Labelling includes not only allergenic foods but also products of such foods. Because allergens are naturally-occurring proteins, the Panel considered whether the definition is too broad in that it may include products that are not allergenic because they do not contain sufficient protein to elicit an allergic reaction. The available data do not, however, permit definition of the amount of allergenic protein necessary to elicit an allergic reaction.

The Panel therefore recommended that products of the allergenic foods on the list of the Codex Committee on Food Labelling should always be labelled as such, unless they are on the list of products that are excluded from the requirement for labelling of the food source.

The criteria for inclusion of a product on the latter list are:

⁴³⁹ https://apps.who.int/iris/bitstream/handle/10665/42378/WHO_TRS_896.pdf

- (i) evidence that a clinical study with a double-blind placebo-controlled food challenge has confirmed that the specific product does not elicit allergic reactions in a group of patients with clinical allergy to the parent foodstuff;
- (ii) submission of specifications for the product and its manufacturing process which demonstrate that the process yields a consistently safe product; and
- (iii) **for products implicated in coeliac disease:**
(a) products of rye, barley and oats would not be required to meet the criteria set out in (i) and (ii) above because IgE-mediated allergic reactions to these cereal grains are uncommon;
(b) products of wheat, spelt and their hybridized strains would be required to meet the criteria set out in (i) and (ii) above; and
(c) products of wheat, rye, barley, oats and spelt and their hybridized strains would be required to adhere to existing specifications for gluten-free products.⁴⁴⁰ (emphasis added)

The FDA's Draft Guidance's Scientific Factors are also not consistent with the 2021 FAO/WHO Expert Consultation" which should have been expressly referenced in the FDA's Draft Guidance, Section IV, Scientific Factors (FDA Ref. 45 in FDA's Draft Guidance) in addition to Ref. 2 and Refs. 25-29.⁴⁴¹

"In May 2021, FAO [Food and Agriculture Organization of the United Nations]/WHO [World Health Organization] issued a summary report, which, among other things, **identified prevalence** of the immune-mediated hypersensitivity to a specific food, **severity** (i.e., proportion of severe objective reactions to a food/ingredient such as anaphylaxis), and the **potency** of food/ingredient (i.e., the amount of the food/ingredient required to cause objective signs) as the three key criteria that should be used to establish the priority allergen list (Ref. 45)."⁴⁴²

The 2021 FAO/WHO Expert Consultation, which was chaired by the FDA's Dr. Lauren Jackson, Chief, Process Engineering Branch, Division of Processing Science & Technology, Institute for Food Safety & Health, determined:

"Based on systematic and thorough assessments which used all three criteria (prevalence, severity and potency), the Committee recommended that the following should be listed as priority allergens: Cereals containing gluten (i.e., wheat and other Triticum species, rye and other Secale species, barley and other Hordeum species and their hybridized strains), crustacea, eggs, fish, milk, peanuts, sesame,

⁴⁴⁰ https://apps.who.int/iris/bitstream/handle/10665/42378/WHO_TRS_896.pdf (Annex 4, pages 126-127)

⁴⁴¹ <http://www.fao.org/3/cb4653en/cb4653en.pdf>

⁴⁴² <https://www.fao.org/3/cb4653en/cb4653en.pdf> , <https://www.cdc.gov/foodsafety/symptoms.html> , and <https://www.cdc.gov/foodsafety/cdc-and-food-safety.html>

specific tree nuts (almond, cashew, hazelnut, pecan, pistachio and walnut).”⁴⁴³ ⁴⁴⁴
(emphasis added)

In order to evaluate the public health importance of food allergens other than the Major Food Allergens, the FDA’s Draft Guidance must include scientific factors using a fair scale and fair metrics. As currently written, the FDA’s Draft Guidance does not do so for Non-IgE-Mediated food allergy mechanisms with Celiac.

D. Recommended Changes to the Scientific Factors in the FDA’s Draft Guidance

In Section IV.A., the header of “Evidence of IgE-mediated Food Allergy” should be changed to “Evidence of IgE-mediated and Non-IgE-mediated Food Allergy”. Additionally, corresponding Non-IgE-mediated food allergy information must be included in that section.

In Section IV.B., the header of “Prevalence of IgE-mediated Food Allergy” should be changed to “Prevalence of IgE-mediated and Non-IgE-mediated Food Allergy”. Additionally, corresponding Non-IgE-mediated food allergy information must be included in that section.

In Section IV.C., the header of “Severity of IgE-mediated Food Allergy” should be changed to “Severity of IgE-mediated and Non-IgE-mediated Food Allergy”. Additionally, corresponding Non-IgE-mediated food allergy information must be included in that section.

In Section IV.D., the “Allergenic Potency” section should include Non-IgE-mediated food allergy with Celiac Disease.

E. FDA’s Exclusive Focus On The Most Severe And Immediately Life-Threatening Allergic Reactions, Including Anaphylaxis Works For Evaluating 160 Typical Food Allergens, But Not For Gluten

The FDA’s Draft Guidance’s exclusive focus on “food allergies that are recognized to be the most severe and immediately life-threatening are those that are mediated by immunoglobulin E antibodies (IgE) because IgE-mediated food allergic reactions are capable of triggering anaphylaxis” is misguided and incongruent with science-based evidence and FDA officials’ recommendations in Ref. 45 (2021 FAO/WHO Expert Consultation). This focus excludes food allergy with Non-IgE-Mediated mechanism with Celiac Disease (othering Celiac) specifically with respect to the immediacy of a severe allergic reaction.

Acuteness - How Quickly Do Food Allergy Symptoms Develop?

According to the Mayo Clinic, “[IgE-Mediated] Food allergy symptoms usually develop within a few minutes to 2 hours after eating the offending food.”⁴⁴⁵

⁴⁴³ “Due to the lack of data on prevalence, severity and/or potency, or due to regional consumption of some foods, the Committee recommended that some of the allergens, ... oats, ... should not be listed as global priority allergens but may be considered for inclusion on priority allergen lists in individual countries.”

⁴⁴⁴ <http://www.fao.org/3/cb4653en/cb4653en.pdf>

⁴⁴⁵ <https://www.mayoclinic.org/diseases-conditions/food-allergy/symptoms-causes/syc-20355095>

For Non-IgE-Mediated mechanisms with Gluten, research from 2016 has shown that “[m]edian time to symptom onset [following Gluten exposure] was 1 hour (range 10 min to 48 h), and median symptom duration was 24h (range 1 h to 8 days).”⁴⁴⁶

According to research published by Sciences Advances on the acuteness of symptom onset in Non-IgE Cell-Mediated Reactions with Celiac Disease in 2019, “Cytokine release and gastrointestinal symptoms after gluten challenge in celiac disease”, if Celiac Disease patients who are following a strict Gluten Free diet “are exposed to gluten-containing food, they typically suffer from gastrointestinal reactions occurring 1 to 2 hours after the gluten exposure.”⁴⁴⁷

With respect to challenging this framework -- the most severe and immediately life-threatening allergic reactions, including anaphylaxis – it is instructive to review a couple of examples of how this framework is not a one size fits all, especially in the context of evaluating the public health importance of labeling Gluten.

Example with Foodborne Illness Using “Immediately Life-Threatening” as a Criteria

Imagine, if in the context of protecting consumers against foodborne illness, the primary focus by the FDA was on the immediacy of a reaction whereby protections against *Staphylococcus aureus* (Staph) were prioritized over *E. coli* (*Escherichia coli*). According to the CDC, *Staphylococcus aureus* (Staph) has symptoms that begin 30 minutes to 8 hours after exposure and include nausea, vomiting, and stomach cramps and diarrhea. With *E. coli* (*Escherichia coli*), symptoms begin 3 to 4 days after exposure and include severe stomach cramps, diarrhea (often bloody), and vomiting. Moreover, around 5-10% of people diagnosed with *E. coli* develop a life-threatening health problem.” It is without question that *E. coli* can be very dangerous, even though symptoms begin 3-4 days after exposure.⁴⁴⁸ Nonetheless, it does not appear that (just because symptoms of Staph can begin 30 minutes after exposure) consumer protection schemes against preventing *Staphylococcus aureus* are prioritized over preventing *E. coli*.

Requiring That Adverse Immunological Reactions Are IgE-Mediated Is A Red Herring, Just Like Saying a Concussion Protocol Should Only Be Undertaken For Head Trauma If A Person Is Knocked Unconscious

As previously addressed in the legislative history of FALCPA, the well-funded food industry lobbied Congress in 2002-2004 for concessions in FALCPA’s mandatory food labeling requirements.

The othering of the consumer protection needs of those with Celiac Disease (a Non-IgE-Mediated adverse reaction, auto-immune disease and digestive disease) was dangerously and scientifically inaccurate. The lobbying disclosures suggest that it was the American Bakers Association and/or the American Farm Bureau which further argued that potentially life-threatening food allergies with Non-IgE-Mediated mechanisms should not be viewed in the same light as those who suffer from potentially life threatening IgE-Mediated food allergies (i.e., peanuts, tree nuts).

The lobbying disclosure statements which appear to have been from the American Bakers Association and/or the American Farm Bureau suggest that these trade organizations led the

⁴⁴⁶ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5283559/>

⁴⁴⁷ Goel et al., *Sci. Adv.* 2019; 5: eaaw7756 7 August 2019, <https://celiac.org/main/wp-content/uploads/2020/03/NexVax2-Study.pdf>

⁴⁴⁸ www.fda.gov/food/consumers/what-you-need-know-about-foodborne-illnesses

charge for the othering of the consumer protection needs of those with Celiac Disease by incorrectly saying that scientifically, Gluten should be viewed as an intolerance and not a food allergy. This was a false premise which was unfortunately not rebutted, or not rebutted well enough, and it ultimately gained strength and support, even though it was dangerously and scientifically inaccurate.

The lobbyists conflated Celiac Disease (a food allergy, auto-immune disease and digestive disease) with Gluten intolerance. Additionally, the information suggests that the food industry othered the public health importance of requiring the labeling Gluten as a food allergen because this Non-IgE-Mediated food allergy is not capable of triggering anaphylaxis and being *immediately* life-threatening, while seemingly ignoring that Celiacs face potentially life-threatening and severe health dangers that can arise through Gluten ingestion including by way of example and not limitation: anemia, cancer, failure to thrive, heart disease, immunological scarring, intestinal damage, malnutrition, etc.

The argument from the food industry circa 2002-2004 that Celiacs do not go into anaphylactic shock from Gluten ingestion is a red herring. That is as uninformed as saying that a concussion protocol should not apply to a person who suffers a head injury, but who does not become unconscious.

Today, we treat all head trauma seriously since there can be critical short and long-term consequences from not implementing a concussion protocol, even if the immediate impact of the head trauma is not visible. In other words, after being exposed to Gluten, Celiac patients such as my son can suffer both serious short-term symptoms such as diarrhea and vomiting, and long-term medical complications including liver disease, inflammatory bowel disease, osteoporosis, neurological conditions, immunological scarring and cancer. That is in part why Gluten must be labeled on all packaged foods for those with Celiac Disease, IgE-Mediated Food Allergies to Grains Containing Gluten and Non-Celiac Gluten Sensitivity.

Take for example the case of a 53-year-old woman with Celiac Disease that was profiled in The New England Journal of Medicine on August 31, 2023,

“A 53-year-old woman with celiac disease was transferred to the intensive care unit (ICU) of this hospital [Brigham and Women’s Hospital] for the management of upper gastrointestinal bleeding with hemorrhagic shock. The patient had been in her usual state of health until approximately 3 weeks before the current presentation, when fatigue, malaise, anorexia, generalized weakness, and watery diarrhea developed. Two weeks later, the diarrhea increased in frequency and became bloody. The patient presented to the emergency department of another hospital for evaluation.”⁴⁴⁹

“Metabolic dysfunction-associated steatotic liver disease (MASLD; formerly known as nonalcoholic fatty liver disease) is a term that encompasses all disease grades and stages and is defined by the presence of macrovascular steatosis in at least 5% of hepatocytes, in the absence of a readily identified alternative cause (e.g., medication, starvation, or a monogenic disorder), in persons who drink little or no alcohol (<20 g per day for women

⁴⁴⁹ “Case 27-2023: A 53-Year-Old Woman with Celiac Disease and Upper Gastrointestinal Bleeding,” Nikroo Hashemi, M.D., M.P.H., Emily W. Lopes, M.D., M.P.H., Ranjodh S. Dhami, M.D., Angela E. Lin, M.D., and Jinesa Moodley, M.D., The New England Journal of Medicine, August 31, 2023, <https://www.nejm.org/doi/pdf/10.1056/NEJMcpc2300903?articleTools=true>

and <30 g per day for men)... This patient has celiac disease, as well as iron and folate deficiencies and bone loss. In patients with celiac disease, the most common manifestation of liver injury (known as ‘celiac hepatitis’) involves elevated levels of alanine aminotransferase and aspartate aminotransferase and mild, nonspecific changes on liver biopsy.^{450 451},⁴⁵²

“Celiac disease is present in 2.2 to 7.9% of patients who have fatty liver and a normal BMI.⁴⁵³ **There is an increased risk of MASLD (hazard ratio, 2.8) among patients with celiac disease who follow a gluten-free diet.**^{454 455} **MASLD occurs in more than one third of patients with celiac disease who follow a gluten-free diet, as compared with 21.8% of patients without celiac disease, and the increased risk persists more than 15 years after celiac disease is diagnosed.**⁴⁵⁶,⁴⁵⁷ (emphasis added)

While we appreciate that there are scientific distinctions in the way that the body reacts to an IgE-Mediated Food Allergy (i.e., wheat allergy) vs. a Non-IgE-Mediated Food Allergy (i.e., Celiac), the bottom line is that what is food for one is poison for another, including for those with Celiac. The FALCPA should have provided equal protection under the law, and it has not for those who live with Celiac, Non-Celiac Gluten Sensitivity and IgE-Mediated food allergies to Grains Containing Gluten.

To reiterate, in addition to other research and arguments set forth in this Citizen Petition, some pundits believe that a strong legal argument could be made for labeling Gluten as a Major Food Allergen under an Equal Protection Clause claim whereby Celiacs have been discriminated against by the FDA. For example, the evidence suggests that FALCPA and the FDA have been using a suspect classification of Gluten as a second-class food allergen and Celiac as not a food allergy, but instead an intolerance, and therefore treating Celiac as much less serious than an IgE-Mediated food allergy. In turn, that suspect classification has then been used as a pretext to

⁴⁵⁰ Rubio-Tapia A, Murray JA. Liver involvement in celiac disease. *Minerva Med* 2008; 99: 595-604.

⁴⁵¹ Villavicencio Kim J, Wu GY. Celiac disease and elevated liver enzymes: a review. *J Clin Transl Hepatol* 2021; 9: 116-24.

⁴⁵² Rinella ME, Neuschwander-Tetri BA, Siddiqui MS, et al. AASLD Practice Guidance on the clinical assessment and management of nonalcoholic fatty liver disease. *Hepatology* 2023; 77: 1797-835.

⁴⁵³ Bardella MT, Valenti L, Pagliari C, et al. Searching for coeliac disease in patients with non-alcoholic fatty liver disease. *Dig Liver Dis* 2004; 36: 333-6.

⁴⁵⁴ Reilly NR, Lebwohl B, Hultcrantz R, Green PHR, Ludvigsson JF. Increased risk of non-alcoholic fatty liver disease after diagnosis of celiac disease. *J Hepatol* 2015; 62: 1405-11.

⁴⁵⁵ Tovoli F, Negrini G, Fari R, et al. Increased risk of nonalcoholic fatty liver disease in patients with coeliac disease on a gluten-free diet: beyond traditional metabolic factors. *Aliment Pharmacol Ther* 2018; 48: 538-46.

⁴⁵⁶ Tovoli F, Negrini G, Fari R, et al. Increased risk of nonalcoholic fatty liver disease in patients with coeliac disease on a gluten-free diet: beyond traditional metabolic factors. *Aliment Pharmacol Ther* 2018; 48: 538-46.

⁴⁵⁷ “Case 27-2023: A 53-Year-Old Woman with Celiac Disease and Upper Gastrointestinal Bleeding,” Nikroo Hashemi, M.D., M.P.H., Emily W. Lopes, M.D., M.P.H., Ranjodh S. Dhami, M.D., Angela E. Lin, M.D., and Jinesa Moodley, M.D., *The New England Journal of Medicine*, August 31, 2023, <https://www.nejm.org/doi/pdf/10.1056/NEJMcpc2300903?articleTools=true>

provide and perpetuate the voluntary labeling scheme of Gluten instead of a mandatory labeling scheme to declare of Gluten on all food packages in the U.S.

F. Mechanism in Action – Cognitive Mechanism

In medicine, mechanism in action is used to describe how a drug or other substance produces an effect in the body.⁴⁵⁸ When it comes to consumer protection and requiring that Gluten be labeled for those with a Celiac food allergy to Gluten, the FDA’s Draft Guidance seems incorrectly anchored on whether or not a food allergy is an IgE-Mediated Mechanism or Non-IgE-Mediated Mechanism.

I would suggest that the FDA view this evaluation of the public health importance of food allergens other than the Major Food Allergens through a more equitable lens and also focus on cognitive mechanisms. With respect to selecting safe foods to consume, including reading food labels, cognitive mechanisms involve the ways in which people receive information, and the ways in which people think about, interpret, evaluate and therefore act upon that information received on food labels (“Cognitive Mechanism”). In marketing, we refer to that as part of consumer behavior.

Before there can be an IgE-Mediated or Non-IgE-Mediated mechanism, there is a Cognitive Mechanism that takes place with selecting safe foods to consume and reading labels. What happens inside the body is a secondary mechanism in action, and as such, cannot be exclusively viewed through that downstream mechanism lens without regard to the initial and primary Cognitive Mechanism, followed by an Ingestion Mechanism.

According to the research entitled, “The Food Allergy Consumer Journey, Defining Challenges, Overcoming Obstacles, Creating a Blueprint for Food Allergen Labeling Success” conducted by McKinsey & Company, Northwestern University and Global Strategy Group for Food Allergy Research & Education (“FARE”), 71% of food allergy consumers “check food labels every time they shop – some for 3-5 minutes per product.”⁴⁵⁹ We can personally attest to that time commitment per product that we spend in trying to purchase safe food products for our 9 year old son, especially in the absence of mandatory labeling of Gluten.

Watch 5th grader [in 2021] Ava Z. from Maryland tell World News Tonight with David Muir how hard it is with the voluntary labeling scheme for Gluten,

“A gluten-free diet is really hard because not all packaged foods are clearly labeled as containing gluten. This makes it really hard to find safe, gluten-free food for people with Celiac disease,” said Ava.⁴⁶⁰

⁴⁵⁸ <https://www.cancer.gov/publications/dictionaries/cancer-terms/def/mechanism-of-action>

⁴⁵⁹ <https://www.foodallergy.org/fare-consumer-journey-infographic> ; and <https://www.foodallergy.org/food-allergy-consumer-journey>

⁴⁶⁰ <https://youtu.be/MSySXOE17k8?t=63>

X. What's Past Suggests Prologue and That's Why We Need Help from President Biden, Secretary Becerra, Commissioner Califf, Deputy Commissioner Jones and the HHS Equity Team

“What's past is prologue!”

--William Shakespeare

“I have the audacity to believe that peoples everywhere can have three meals a day for their bodies, education and culture for their minds, and dignity, equality, and freedom for their spirits.”

-- Dr. Martin Luther King, Jr.

A. Overview

In “The Tempest,” Antonio’s words -- “what’s past is prologue” -- have come to convey a double meaning. The optimistic interpretation is that historical actions that have transpired prepare us for opportunities to come. In other words, what’s already happened sets the stage for the really important work that can lead to uplifting empathy, change, happiness and peace. The alternate, more cynical view, would be that what took place in the past inevitably repeats itself because we do not learn from our experiences and mistakes.

As it pertains to the FDA’s Draft Guidance, is the FDA destined to repeat its mistakes of the past or can the past inform the present to take care of underserved communities like the Celiac community with mandatory labeling of Gluten on packaged foods? Unfortunately, the FDA’s Draft Guidance suggests a more cynical view -- a gut-wrenching reminder of how far we have yet to travel as a nation -- that what took place in the past 19 years inevitably repeats itself because the FDA has not learned from its mistakes and shortcomings.

B. Ask the FDA Webinar

On October 13, 2022, there was an “Ask the FDA Webinar” in which Marilyn Geller, CEO of the Celiac Disease Foundation, asked Robin McKinnon, PhD, Senior Advisor for Nutrition Policy, FDA Center for Food Safety and Applied Nutrition (CFSAN), about whether Gluten would ever be declared as a Major Food Allergen and how the FDA’s Draft Guidance seemingly precluded such evaluation of the public health importance of the labeling of Gluten.⁴⁶¹

Dr. McKinnon’s answer was disheartening, especially since her statement occurred two months after the period for submission of comments on the FDA’s Draft Guidance closed on August 16, 2022. Dr. McKinnon did not even acknowledge the 1,576 comments submitted (82.8% of all comments submitted) to the FDA’s Draft Guidance regarding the labeling of Gluten and/or Celiac Disease. Further, Dr. McKinnon did not even acknowledge that the FDA was even contemplating revising the FDA’s Draft Guidance to include Non-IgE-Mediated food allergy with Gluten. Instead, Dr. McKinnon’s response suggested a doubling down on the IgE-Mediated requirement in the FDA’s Draft Guidance for the FDA to even evaluate of the public health importance of food allergens other than the Major Food Allergens. Dr. McKinnon stated, “**The draft guidance includes information on how stakeholders can submit requests to FDA on those allergens and how FDA will evaluate the data in those submissions.**”⁴⁶² (emphasis added)

⁴⁶¹ https://www.youtube.com/watch?v=Ay3h_4ArOqk&t=2259s

⁴⁶² https://youtu.be/Ay3h_4ArOqk?t=2259

Dr. McKinnon's comments reenforce the pernicious impact of the FDA's suspect classification (must be IgE-Mediated food allergy instead of Non-IgE-Mediate food allergy) for the evaluation of Gluten as a Major Food Allergen by creating a false framework for the science behind how the public health importance with the labeling of Gluten will be evaluated. The FDA's Draft Guidance expressly states, "This guidance is intended for:

- **FDA staff who are responsible for evaluating, on FDA's initiative or in response to a citizen petition submitted in accordance with 21 CFR 10.30,** the public health importance of a non-listed food allergen, which for the purpose of this guidance means a food allergen other than one of the major food allergens (i.e., milk, eggs, fish, Crustacean shellfish, tree nuts, wheat, peanuts, soybeans, and sesame⁴⁶³) listed in the Federal Food, Drug, and Cosmetic Act (FD&C Act); and
- **Stakeholders who intend to submit a citizen petition asking FDA to establish regulatory requirements based on the public health importance of a non-listed food allergen ("applicable stakeholders") or who are interested in how FDA generally intends to evaluate the public health importance of such food allergens.**⁴⁶⁴ (emphasis added)

Moreover, the FDA's actions with the citizen petition filed on September 10, 2008 to label Gluten suggests that past will be prologue in that any new citizen petition on the labeling of Gluten would be subject to the same decade long delay of no action only to be followed by being summarily denied "because the petition did not include adequate information to show that rye and barley are common causes of severe IgE-mediated food allergies (Ref. 22)."⁴⁶⁵

C. Historical Shortcomings: 1985-2022

In addition to FALCPA falling short, it is instructive to review how the FDA fell short for a decade in terms of implementing the Congressional mandate of providing consumer protection to the Celiac community. After FALCPA was signed into law by President George W. Bush on August 2, 2004, mandatory labeling of the top 8 Major Food Allergens began on January 1, 2006 (Public Law No: 108-282). However, it took the FDA a decade to implement the voluntary labeling scheme of Gluten Free products on August 5, 2014 (six years past the Congressionally imposed deadline). Congress, consumers and scientists were outraged with the FDA slow-walking this process which lagged behind peer counties to the United States.

Prior to FALCPA, there was a prevailing school of thought with the assumption of risk, "caveat emptor" or let the buyer beware. FALCPA helped to mitigate allergic responses to the top 8 Major Food Allergens, but with respect to the Celiac community and allergic responses to Gluten, the slow walk of the FDA in undertaking the Gluten Free final rule in 2014 suggested an

⁴⁶³ "In April 2021, the Food Allergy Safety, Treatment, Education, and Research Act of 2021 (FASTER Act) amended section 201(qq) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) to add sesame to the definition of major food allergen. This amendment applies to any food that is introduced or delivered for introduction into interstate commerce on or after January 1, 2023 (Public Law 117-111)." <https://www.fda.gov/media/157637/download>

⁴⁶⁴ <https://www.fda.gov/media/157637/download>

⁴⁶⁵ FDAs Draft Guidance, and Ref. 18: Citizen Petition CP-2008-P-0509, received September 10, 2008, submitted by Hallie Jane Davis, Docket No. FDA-2008-P-0509, Document ID FDA-2008-P-0509-0001 and Ref. 22: Letter dated February 6, 2018, from Douglas Stearn of FDA to Hallie Jane Davis. Available at <https://www.regulations.gov>, Docket No. FDA-2008-P-0509, Document ID FDA-2008-P-0509-0007, <https://www.regulations.gov/docket/FDA-2008-P-0509/document>

indifference to the saying, let the buyer be ill, and the consumer protection needs of the Celiac community.

According to the FALCPA of 2004,

“Not later than 2 years after the date of enactment of this Act [August 2, 2006], the Secretary of Health and Human Services, in consultation with appropriate experts and stakeholders, shall issue a proposed rule to define, and permit use of, the term ‘gluten-free’ on the labeling of foods. Not later than 4 years after the date of enactment of this Act [August 2, 2008], the Secretary shall issue a final rule to define, and permit use of, the term ‘gluten-free’ on the labeling of foods.”⁴⁶⁶

On January 23, 2007, the FDA published its proposed rule on the voluntary labeling of Gluten Free products.⁴⁶⁷ that for all intents was the final rule ultimately enacted on August 5, 2014. At that point in 2007, the U.S. lagged way behind our peer countries which had all set labeling standards for Gluten Free foods. This unnecessary delay happened notwithstanding the House of Representatives Report on FALCPA stating, “[g]iven the devastating nature of celiac disease, the Committee urges the Secretary to move expeditiously in implementing the requirements of this section.”⁴⁶⁸ The FDA had acknowledged that FALCPA required the FDA to issue a proposed rule that will define and permit the voluntary use of the term Gluten Free on the labeling of foods by August 2006 and a final rule no later than August 2008.⁴⁶⁹

Perfect is the Enemy of Good

While the consumer protections established by FALCPA and the FDA were far from perfect, the protections were a step in the right direction. That said, in reflecting on the decade long process to implement voluntary Gluten Free labeling, Voltaire’s “perfect is the enemy of good” comes to mind.

On April 28, 2011, The Washington Post reported,

“For seven years, the Food and Drug Administration has been trying to answer this question: What does it mean to be gluten-free? That is roughly the time it took to build a tunnel beneath the English Channel to connect Britain and France... Three years after the congressional deadline [in 2008 to define a Gluten Free rule as mandated by FALCPA], the FDA is still working on that question, a spokeswoman said. The agency has said the issue is complicated, requiring analyses of various technical issues, including how well manufacturers and regulators can reliably test for the presence of gluten and whether oats are a source of gluten. The agency held a public meeting in 2005, inviting input from millers, foodmakers, medical experts and others, and published a proposed rule in 2007. And then it continued to study the matter. **Meanwhile, Canada, Brazil, Australia and an international body -- the Codex Alimentarius Commission -- have all set labeling**

⁴⁶⁶ <https://www.fda.gov/food/food-allergensgluten-free-guidance-documents-regulatory-information/food-allergen-labeling-and-consumer-protection-act-2004-falcpa>

⁴⁶⁷ <https://www.govinfo.gov/content/pkg/FR-2007-01-23/pdf/FR-2007-01-23.pdf>

⁴⁶⁸ H.R. Rep. No. 108-608, at 18. (2004), <https://www.congress.gov/108/crpt/hrpt608/CRPT-108hrpt608.pdf>

⁴⁶⁹ <https://www.fda.gov/food/food-allergensgluten-free-guidance-documents-regulatory-information/food-allergen-labeling-and-consumer-protection-act-2004-questions-and-answers#q21>

standards for gluten-free items. In most cases, that standard is 20 parts per million:

A food can be labeled gluten-free if it contains less than 0.0007 of an ounce of gluten for every 2.2 pounds of food. That level was chosen largely because it's the minimum amount of gluten that can be reliably detected."⁴⁷⁰

"Under a 2004 law, Congress gave the FDA until 2008 to establish a uniform definition for companies that want to label their products as gluten-free. But that deadline has come and gone.

'The FDA has spent years calling upon experts to have open-forum debates, town hall meetings — we've been having reiteration and reiteration,' said Alessio Fasano, medical director of the Center for Celiac Research at the University of Maryland School of Medicine. 'They've been reiterating and listening to Grandma, Grandpa, people on the street corners... I really don't understand why it's lingering up in the air when it really should be a no-brainer.'"⁴⁷¹

"And that [3 years after deadline, FDA still has not defined gluten-free] has caused an explosion in gluten-free foods. The market is projected to reach \$2.6 billion next year, up from \$100 million in 2003. Gluten-free cereal, snacks and other foods carry a premium price, creating an alluring growth market for food companies."⁴⁷²

Let Them Eat Cake

In May 2011, seven years after FALCPA was signed into law, John Forberger,⁴⁷³ a triathlete, and Jules Shepard,⁴⁷⁴ author of "The First Year: Celiac Disease and Living Gluten-Free," were frustrated by the lack of progress by the Federal government on the labeling to protect the Celiac community. As part of the Gluten Free Food Labeling Summit, these patient advocates developed a plan to build the world's tallest Gluten Free cake.⁴⁷⁵ Mr. Forberger and Ms. Shepard rallied leaders throughout the Celiac community including Dr. Fasano, Rep. Lowey and FDA Deputy Commissioner Taylor to join them on May 4, 2011, in Washington, D.C. to kick-off Celiac Awareness Month. Their goal was to refocus attention on the way overdue labeling rules to protect the Celiac community. Their effort, along with the weight of the world's largest gluten-free cake, had an impact that resonated across the country.

⁴⁷⁰ https://www.washingtonpost.com/politics/3-years-after-deadline-fda-still-hasnt-defined-gluten-free/2011/04/22/AFRq6i8E_story.html

⁴⁷¹ https://www.washingtonpost.com/politics/3-years-after-deadline-fda-still-hasnt-defined-gluten-free/2011/04/22/AFRq6i8E_story.html

⁴⁷² https://www.washingtonpost.com/politics/3-years-after-deadline-fda-still-hasnt-defined-gluten-free/2011/04/22/AFRq6i8E_story.html

⁴⁷³ <https://www.rutgers.edu/news/rutgers-alum-leads-efforts-protect-those-celiac-disease>

⁴⁷⁴ <https://gfjules.com/how-we-built-the-world-s-tallest-gluten-free-cake-and-why/>

⁴⁷⁵ <https://web.archive.org/web/20110511034354/http://1in133.org/>



World's Largest Gluten Free Cake, Gluten Free Labeling Summit,
Embassy Suites D.C., Convention Center, Washington, D.C., May 4, 2011

On August 10, 2011, Mike Taylor, former FDA Deputy Commissioner for Food and Veterinary Medicine, who wrote an article, “Why the Government is Regulating Gluten-Free Foods” in The Atlantic,

“For people with celiac disease, gluten can cause serious health conditions. It’s time for them to know their food is safe... **We pledged to move promptly to issue a final rule defining ‘gluten free’ next year [2012].** This will have a real impact on consumers with celiac disease who now have to navigate the ‘gluten free’ labels on their grocery store shelves hoping that consuming a particular product won’t bring on any of the painful symptoms of their illness, such as abdominal pain or vomiting. Or worse yet lead to chronic serious health effects such as infertility or intestinal cancers, because exposure to gluten over time can rob their bodies of the ability to properly absorb nutrients from foods.”⁴⁷⁶ (emphasis added)

On October 2, 2012, consumer frustration with the FDA missing the 2008 Congressionally imposed deadline to establish a Gluten Free labeling scheme grew. One example manifested itself when a consumer, “J.I.”, posted a petition on the White House Web site for President Barack Obama which stated, “WE THE PEOPLE ASK THE FEDERAL GOVERNMENT TO TAKE OR EXPLAIN A POSITION ON AN ISSUE OR POLICY: Finalize Standards for GLUTEN-FREE Labeling.”

⁴⁷⁶ <https://www.theatlantic.com/health/archive/2011/08/why-the-government-is-regulating-gluten-free-foods/243415/>

The October 2, 2012 petition was signed by 40,639 people, and Michael Taylor, Deputy Commissioner for Foods and Veterinary Medicine at the Food and Drug Administration, only responded on or after August 5, 2013 (when the long-delayed proposed Final Rule was issued).⁴⁷⁷

On February 14, 2013, Dr. Whitney Caudill of Manchester College of Pharmacy in Indiana wrote an article, “A response to Verrill et al: Food label usage and reported difficulty with following a gluten-free diet among individuals in the USA with coeliac disease and those with noncoeliac gluten sensitivity”,

“I have coeliac disease (“CD”). CD is a systemic autoimmune disorder caused by exposure to gluten in genetically susceptible people. (Fasano & Catassi, 2012). Gluten is a protein found in wheat, rye, and barley and the derivatives of each. The immune response activated in CD causes the body to attack gluten as if it is an antigen and cause symptoms including chronic diarrhea, weight loss, bloating, and chronic fatigue, among others. (Fasano & Catassi, 2012). Untreated CD can result in osteoporosis, neurologic disorders, and cancer. (Fasano & Catassi, 2012)...

In order for a product to be gluten-free it must be safely free of all gluten: wheat, barley, and rye. Unfortunately, the current law does not meet that standard. The definition of major food allergen includes only wheat. 21 U.S.C. § 321(qq) (2012). It does not include rye and barley, and the derivatives, all of which contain gluten. **The FDA’s definition of major food allergen must include the term ‘gluten’ or the words ‘wheat, barley, and rye’ to safely protect citizens with CD or NCGS.**

Additionally, the FALCP [sic – “FALCPA”] charged the FDA to have final standards for gluten-free labeling in place by 2008, no later than four years after the enactment of FALCP. Food Allergen Labeling and Consumer Protection Act of 2004, Pub. L. no. 108-282, 118 Stat. 910 (2004). In 2007, following up on the mandate from FALCP, the FDA issued a proposed rule: ‘Food labeling; Gluten-Free Labeling of Foods.’ The proposed rule states that a food is gluten-free if the food does not contain any of the following:

1. an ingredient that is any type of wheat, rye, barley, or crossbreeds of these grains;
2. an ingredient derived from these grains and that has not been processed to remove gluten;
3. an ingredient derived from these grains and that has been processed to remove gluten, if it results in the food containing 20 or more parts per million (ppm) gluten; or
4. 20 ppm or more gluten.

Food Labeling; Gluten-Free Labeling of Foods, 72 Fed. Reg. 2795 (proposed January 23,

⁴⁷⁷ “The Food Allergen Labeling and Consumer Protection Act required Health and Human Services to set a gluten-free labeling rule by 2008 to aid people with celiac disease, a life-threatening autoimmune condition. The only known treatment is a strict gluten-free diet. An estimated 3 million Americans have celiac and even more may have non-celiac gluten sensitivity. Without adequate labeling, those on a medically prescribed gluten-free diet struggle to make safe food choices and stay well. Children with celiac cannot participate in the National School Lunch Program when food service staff cannot determine if products are gluten-free. Congress did its part by passing the law. It is up to the White House to protect the health of millions of adults and children by finalizing the rule NOW.” Source: <https://petitions.obamawhitehouse.archives.gov/petition/finalize-standards-gluten-free-labeling/>

2007) (to be codified at 21 CFR Part 101).⁴⁷⁸ These standards are consistent with those adopted in Europe in 2012. (Verrill, *et al.*, 2013)...

It has been nearly a decade since the FDA was empowered by Congress to establish final rules on gluten-free labeling in the United States. The FDA has taken no final action. The FDA has acknowledged that the lack of standards for gluten-free labeling has created difficulty for patients with CD and NCGS to successfully adhere to the medically required GFD. The FDA has stated that ‘more research is needed in this area.’ (Verrill, *et al.*, 2013). Yet, the FDA has not acted on rules it proposed over five years ago that could assist patients who must adhere to a GFD. It is time for the FDA to take action.”⁴⁷⁹

On July 15, 2013, Rep. Nita Lowey, one of the original sponsors of FALCPA stated,

“I am frustrated that, a decade since the passage of the Food Allergen Labeling and Consumer Protection Act, the FDA has yet to lay out clear standards for the regulation of Gluten Free labeling.”⁴⁸⁰

On August 5, 2013, the FDA proposed a Final Rule, “Food Labeling; Gluten-Free Labeling of Foods” with a compliance date of this final rule set as August 5, 2014.⁴⁸¹ According to Dr. Linda Verrill with the FDA’s Center for Food Safety and Applied Nutrition,

“To comply with a directive in FALCPA, in 2007, the FDA published a proposed rule identifying the criteria the agency proposed to use to define the term GF for voluntary use on the labels of foods under FDA’s regulatory purview (US Food and Drug Administration, 2007). In addition to other possible requirements related to the definition of GF, this rulemaking proposed that a food labelled GF cannot contain 20 or more parts per million (ppm) gluten.”⁴⁸²

On August 5, 2014, Mr. Taylor also wrote a “New Era of Gluten Free Labeling”, “For most of us, choosing a meal is not a make or break decision. Most people prepare a meal without fearing that it will endanger their health. That’s not the case with people who suffer from celiac disease.

⁴⁷⁸ <https://www.govinfo.gov/content/pkg/FR-2007-01-23/pdf/FR-2007-01-23.pdf>

⁴⁷⁹ “In Response: It is Time for Action by the United States Food and Drug Administration on Gluten-Free Labeling Rules”, Whitney Jane A. Caudill, J.D., Associate Dean for Administration & Finance, Associate Professor, Manchester University College of Pharmacy”, February 14, 2013, <https://journalofhumannutritionanddieteticseditor.wordpress.com/2013/02/14/a-response-to-verrill-et-al-food-label-usage-and-reported-difficulty-with-following-a-gluten-free-diet-among-individuals-in-the-usa-with-coeliac-disease-and-those-with-noncoeliac-gluten-sensitivity/>

⁴⁸⁰ <https://www.beyondceliac.org/celiac-news/gluten-in-medicine-disclosure-act-an-interview-with-new-york-state-rep-nita-lowey/>

⁴⁸¹ <https://www.federalregister.gov/documents/2013/08/05/2013-18813/food-labeling-gluten-free-labeling-of-foods>

⁴⁸² Verrill, L *et al.* “Food label usage and reported difficulty with following a gluten-free diet among individuals in the USA with coeliac disease and those with noncoeliac gluten sensitivity.” *Journal of human nutrition and dietetics: the official journal of the British Dietetic Association* vol. 26,5 (2013): 479-87. doi:10.1111/jhn.12032, and <https://onlinelibrary.wiley.com/doi/10.1111/jhn.12032>

I've learned first-hand from talking with people with the disease how much it means to them to be able to select gluten-free foods with confidence.”⁴⁸³

According to the FDA,⁴⁸⁴ “[o]n August 2, 2013, FDA issued a final rule⁴⁸⁵ defining ‘Gluten-free’ for food labeling, which is helping consumers, especially those living with celiac disease, be confident that items labeled “gluten-free” meet a defined standard for gluten content. ‘Gluten-free’ is a voluntary claim that can be used by food manufacturers on food labels if they meet all the requirements of the regulations.”

The final rule was implemented as of August 5, 2014 for voluntary labeling of “Gluten Free” claims by manufacturers.

In other words, from August 2, 2004 (when the FALCPA was enacted by President George W. Bush) until August 5, 2014 (when the FDA’s final rule for Gluten Free labeling went into effect), 3,656 days had elapsed! **That was 10 years and 4 days**, but who’s counting? I’ll tell you who has been counting. The Celiac community was counting.

Figure 9 - Summary of the FDA’s Key Delays for Consumer Protections of the Celiac Community

From	When	To	When	Total Time Elapsed
August 2, 2004	FALCPA was enacted by President George W. Bush	January 1, 2006	Mandatory labeling of the top 8 Major Food Allergens began	517 days, or 1 year, 4 months, 30 days
August 2, 2004	FALCPA was enacted by President George W. Bush	August 5, 2014	FDA’s final rule for Gluten Free labeling went into effect	3,654 days, or 10 years and 4 days
August 2, 2008	FDA was supposed to implement voluntary Gluten Free labeling	August 5, 2014	FDA’s final rule for Gluten Free labeling went into effect	2,195 days, or 6 years and 4 days
January 1, 2006	Mandatory labeling of the top 8 Major Food Allergens began	August 5, 2014	FDA’s final rule for Gluten Free labeling went into effect	3,139 days, or 8 years, 7 months and 5 days

⁴⁸³

https://web.archive.org/web/20150418221744/http://blogs.fda.gov/fdavoices/index.php/2014/08/a-new-era-of-gluten-free-labeling/?source=govdelivery&utm_medium=email&utm_source=govdelivery

⁴⁸⁴ “Gluten-Free Labeling of Foods.” U.S. Food & Drug Administration, 7 March 2022.

<https://www.fda.gov/food/food-labeling-nutrition/gluten-free-labeling-foods> . Accessed 13 May 2022.

⁴⁸⁵ “Food Labeling; Gluten-Free Labeling of Foods.” Federal Register, 5 August 2013.

<https://www.federalregister.gov/documents/2013/08/05/2013-18813/food-labeling-gluten-free-labeling-of-foods> . Accessed 13 May 2022.

January 23, 2007	FDA issued a proposed rule for voluntary Gluten Free labeling ⁴⁸⁶	August 5, 2014	FDA's final rule for Gluten Free labeling went into effect	2,752 days, or 7 years, 6 months, and 14 days
August 10, 2011	FDA Deputy Commissioner Taylor pledged in The Atlantic to move promptly to issue a final rule defining 'gluten free' in 2012	August 5, 2013	FDA's final rule for voluntary Gluten Free labeling was proposed	727 days, or 1 year, 11 months, 27 days

Threshold Levels

It is instructive to note that Congress and the FDA have supported the mandatory labeling of the Major Food Allergens since the passage of FALCPA in 2004, even in the absence of known threshold levels for the Major Food Allergens from 2004 to the present. For example, in a "Conversation with the FDA's Stefano Luccioli, M.D.", Dr. Luccioli discussed threshold levels,

"A threshold can mean a lot of things to different people. There can be an individual threshold for food allergens, which is the amount of an allergenic food protein a person has to consume before there is an adverse allergic reaction. Within the allergic population, individual thresholds may vary greatly. For example, some people allergic to peanuts may experience a reaction from a tiny amount, even a few milligrams of peanut, which is equivalent to grains of sand. Others may need to eat a gram or more, equivalent to whole peanuts. **They are all allergic, but their individual thresholds are different.**

There can also be a population threshold. This threshold can be derived from assessing a large number of individual patient thresholds and can be used to predict reaction risks within the food allergic population to certain levels or doses of allergen. Information from population threshold data has been used by some countries to establish reference limits for allergens that may or may not need to bear an allergen advisory statement to protect public health. This is an important area of study and FDA scientists are currently involved in international discussions conducted by the Codex Alimentarius and other authoritative bodies on this topic.

As of now, the FDA has not established thresholds for any major food allergen.

However, this does not mean that we do not consider information related to allergen thresholds in our regulatory work. For example, the FDA may consider allergen threshold data in assessing the safety of ingredients exempted from FALCPA allergen labeling requirements. We continue to monitor and evaluate new science that has emerged in the past decade on population threshold dose response to a variety of food allergens."⁴⁸⁷ (emphasis added)

⁴⁸⁶ <https://www.govinfo.gov/content/pkg/FR-2007-01-23/pdf/FR-2007-01-23.pdf>

⁴⁸⁷ <https://www.fda.gov/food/conversations-experts-food-topics/current-food-allergen-landscape>

According to the FDA, “There is no cure for celiac disease and the only way to manage the disease is to avoid eating gluten. Without a standardized definition of ‘gluten-free,’ these consumers could never really be sure if their body would tolerate a food with that label.”⁴⁸⁸

So why was the FDA seemingly not concerned about thresholds with the Major Food Allergens, even though the FDA endorsed and implemented mandatory labeling schemes of the Major Food Allergens? Compare this with Gluten which was not required to be labeled, but which the FDA delayed even voluntary labeling of for over a decade. It seems that had Gluten just been required to be labeled as a Major Food Allergen, that would have served as the floor of consumer protection upon which years later the Gluten Free Final Rule (i.e., the 20ppm threshold), could have been a complementary consumer protection. This is a just another curious example of the othering of the consumer protection needs of the Celiac community.

Celiacs Historically Have Received Half a Loaf at Twice the Price

Based on feedback from various members in the Celiac community and extensive research, we believe that the FDA has had a long-standing implicit bias against the Celiac community with respect to their medically required dietary needs. The analysis suggests that there has been a dietary disconnect to recognizing the public health importance of the consumer protection needs of the Celiac community. See also section in this Citizen Petition entitled, “The Economics of Celiac Disease with the Financial Burden of the Gluten Free Diet” and Figure 8-10 herein for Market Shopping in the Philadelphia Area as of July 10, 2022.

D. Google Trends for Search Requests on Celiac Disease, Gluten & Gluten Free

It is instructive to review Google Trends⁴⁸⁹ with the actual search requests made to Google for: “celiac”, “celiac disease”, “gluten” and “gluten free” from January 2004 to May 2022. While the searches for “celiac” and “celiac disease” appear to have remained relatively flat over the 18 year period, there was a significant upward trend in search requests for “gluten” and “gluten free” that peaked in May 2014 and have continued in a robust manner through to the present.⁴⁹⁰

The spike in searches for “gluten” and “gluten free” from mid-2013 to mid-2014 correlates with the Gluten Free final rule and the Gluten Free fad diet.

On November 21, 2014, Amanda Topper, Director of US Research: Food, Drink, Foodservice, Flavors & Ingredients, at Mintel, stated,

“Non-Celiacs drive Gluten-Free market growth... Many consumers continue to perceive a gluten-free diet as healthier and helpful for weight loss, despite evidence as such. It is these

⁴⁸⁸ <https://www.fda.gov/consumers/consumer-updates/gluten-free-means-what-it-says>

⁴⁸⁹ “Google Trends provides access to a largely unfiltered sample of actual search requests made to Google. It’s anonymized (no one is personally identified), categorized (determining the topic for a search query) and aggregated (grouped together). This allows us to display interest in a particular topic from around the globe or down to city-level geography.”

<https://support.google.com/trends/answer/4365533?hl=en>

⁴⁹⁰

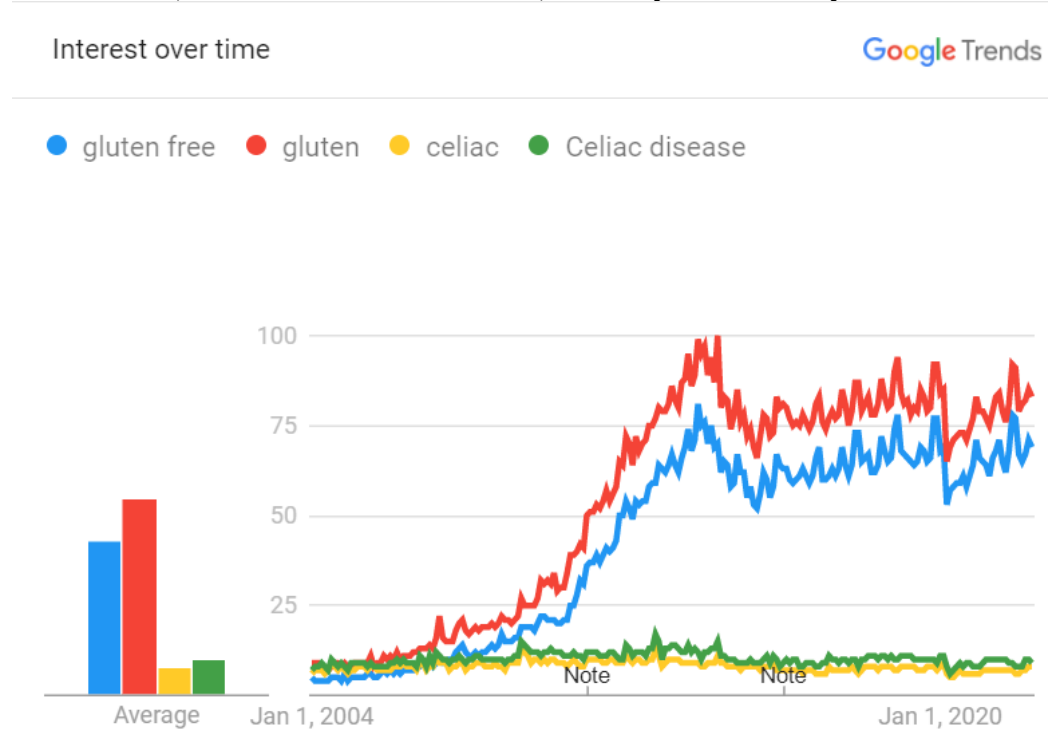
<https://trends.google.com/trends/explore?date=all&geo=US&q=gluten%20free,gluten,celiac,%20Fm%20h1pq>

consumers, not those who have to eat a gluten-free diet for medical reasons, who are driving market growth.”⁴⁹¹

The information suggests that the voluntary labeling scheme of Gluten Free food has been conflated with the voluntary adoption of a GF diet. The information further suggests that a voluntary Gluten Free diet gets conflated with Celiac Disease, a Non-IgE-Mediated food allergy. In turn, since Gluten is not required to be labeled as a Major Food Allergen, that has adversely impacted the Celiac community over time in terms of obfuscating our community’s medical needs and the seriousness with which others perceive the medically required Gluten Free diet.

Our research suggests that the medical requirement for a strict Gluten Free diet coupled with the voluntary labeling of Gluten under FALCPA have converged to provide “medical legitimacy” to those who choose to eat Gluten Free. Conversely, to those with Celiac, the voluntary labeling of Gluten and not referring to a Celiac as a food allergy and Gluten as a food allergen, has led to undermining the medical legitimacy of the only treatment available for Celiac – a strict Gluten Free diet. That said, Gluten appears to be uniquely positioned among the potentially life-threatening food allergens, as the only one which has been widely adopted as a lifestyle choice by those who do not medically require avoiding Gluten in their diets.

Figure 10 - Google Trends – Interest Over Time in Search Requests for Terms: Gluten, Gluten Free, Celiac and Celiac Disease, January 2004 to May 2022



E. Dietary Misappropriation of Gluten Free

According to the Cambridge Dictionary, cultural misappropriation is defined as “the act of taking or using things from a culture that is not your own, especially without showing that you

⁴⁹¹ <https://www.mintel.com/blog/food-market-news/gluten-free-consumption-trends>

understand or respect this culture.”⁴⁹²

Along those lines, we suggest that there has been a dietary misappropriation of the medical needs of the Celiac community by a lot of companies (food manufacturers and restaurant operators) which offer expensive Gluten Free foods and/or market “Gluten Free” foods that are not necessarily Gluten Free (often because of the potential for cross contact as in restaurant settings). In other words, one of the many challenges is that the medical requirement of a strict Gluten Free diet is not taken seriously, and it also has been dietarily misappropriated by companies putting their profits ahead of the medical needs of 3.3 million Americans with Celiac Disease.

F. Assuming That The Food Product Contains Gluten

On January 30, 2022, “The Times and Democrat” newspaper in Orangeburg, South Carolina, added some timely flavor in an article on Gluten labeling and explained some of the challenges with voluntary labeling of Gluten and why we want to have Gluten added to the list of Major Food Allergens and labeled on all packaged foods.

“How do you know whether a food contains gluten? **If a food product is not labeled gluten-free you must assume that the product contains gluten.** Gluten-free labeling is voluntary for all packaged foods that are regulated by the FDA... Labeling is voluntary; therefore, it is the manufacturer’s decision whether to label their gluten-free products.”⁴⁹³ (emphasis added)

Wheat is required to be labeled, but Gluten is not. Gluten is found in Wheat, Barley, Rye and most Oats. Just because something is Wheat free does not mean its Gluten Free. Unlike the Food Allergen Labeling and Consumer Protection Act (FALCPA) labeling scheme for the top 9 Major Food Allergens in the U.S. (Sesame as of 1/1/23), Gluten Free labeling is permissive, not mandatory in the U.S. In other words, whereas sufferers of the current top 9 major food allergens rely on what ingredients are included in required labeling disclosures of packaged foods, Celiacs must rely only on what ingredients are excluded in voluntary Gluten Free labeling disclosures on packaged foods.

If someone has a nut allergy, that person can rely on a food manufacturer being required to label whether a food product has nuts in it. If someone has Celiac Disease, that person can’t rely on food manufacturers labeling Gluten in a food product. Instead, Celiacs must rely on what ingredients are not included in voluntary Gluten Free labeling on food products. That is not very fair and not very safe!

By way of example and not limitation, following are some historical examples of consumer and Celiac advocacy frustration with the FDA:

G. Example 1 – March 6, 1985, FDA’s Failure to Appreciate That Wheat Gluten is But the Tip of the Iceberg in Terms of Ingredients that Celiacs Must Avoid

When Food Is Poison memorialized the following labeling failure from 1985,

⁴⁹² <https://dictionary.cambridge.org/dictionary/english/cultural-appropriation>

⁴⁹³ https://thetandd.com/from-attic-to-basement-gluten-labeling/article_4ca50969-d47a-5cc5-bde1-77c78896ef61.html

“For instance, in 1985, FDA required the specific source of ‘gluten’ be identified on the label when it issued regulations recognizing as generally recognized as safe (GRAS) ‘corn gluten’ and ‘wheat gluten.’ 21 C.F.R. 184.1321-. 1322; 50 Fed. Reg. 8997, 8998 (Mar. 6, 1985). FDA stated it believed gluten-sensitive individuals were adequately safeguarded and rejected consumer requests calling for the mandatory identification of products as ‘gluten-free.’ FDA’s stated rationale was that, because the source of gluten (wheat or corn) must be identified by name, ‘the labeling already required is adequate to alert the public and protect gluten-sensitive individuals.’ 50 Fed. Reg. 8997, 8997 (Mar. 6, 1985). **Although a ‘gluten-free’ standard was likely scientifically infeasible at the time, FDA’s statement nevertheless reflects a failure to appreciate the fact that ‘wheat gluten’ is but the tip of the iceberg in terms of ingredients that individuals sensitive to gluten must avoid, and that identification of ‘wheat gluten’ on the label would be only a partial remedy for people with celiac disease in contrast to ‘gluten-free’ labeling.**”⁴⁹⁴ (emphasis added)

H. Example 2 – September 10, 2008: Citizen Petition to Label Barley and Rye in 2008

According to the FDA’s Draft Guidance,

“In 2008 [September 10], we [FDA] received a citizen petition asking us to [amend] ... FALCPA to include barley and rye in the list of common allergens requiring disclosure on packaging (Ref. 18)... In 2018 [February 6], **“We [FDA] denied the request regarding barley and rye because the petition did not include adequate information to show that rye and barley are common causes of severe IgE-mediated food allergies** (Ref. 22).”⁴⁹⁵ (emphasis added)

First, it is important to note that there was a 10 year delay from 2008-2018 (encompassing three different Presidential administrations for President George W. Bush, 2001-2009; President Barack Obama, 2009-2017; and President Donald Trump, 2017-2021) for the FDA to summarily deny the petition based on a pretext that the petition did not include adequate information to show that rye and barley are common causes of severe IgE-mediated food allergies

On February 6, 2018 (in response to the citizen petition filed almost a decade earlier on September 10, 2008), Douglas Stearn Deputy Director, Center for Food Safety and Applied Nutrition, U.S. Food and Drug Administration, wrote,

“Your petition does not include adequate information to show that rye and barley are common causes of severe immunoglobulin E (IgE)-mediated allergies, such as wheat and other major food allergens under FALCPA. Rather, your petition focuses on the needs of people with celiac disease, which we have taken steps to address. Your citizen petition

⁴⁹⁴ Derr, Laura E. “When Food Is Poison: The History, Consequences, and Limitations of the Food Allergen Labeling and Consumer Protection Act of 2004.” Food and Drug Law Journal, vol. 61, no. 1, 2006, pp. 65–165, <http://www.jstor.org/stable/26660870>, Footnote 196, Page 98. Accessed 16 May 2022.

⁴⁹⁵ FDA’s Draft Guidance, and Ref. 18: Citizen Petition CP-2008-P-0509, received September 10, 2008, submitted by Hallie Jane Davis, Docket No. FDA-2008-P-0509, Document ID FDA-2008-P-0509-0001 and Ref. 22: Letter dated February 6, 2018, from Douglas Stearn of FDA to Hallie Jane Davis. Available at <https://www.regulations.gov>, Docket No. FDA-2008-P-0509, Document ID FDA-2008-P-0509-0007, <https://www.regulations.gov/docket/FDA-2008-P-0509/document>

provides as a statement of grounds: ‘It has been shown that celiacs are not just sensitive to wheat, but are also sensitive to the gluten of rye and barley’ (Petition at page 1). **We agree with this statement and note that information voluntarily provided on food labels concerning the absence of gluten-containing grains may provide additional label information that is helpful to consumers seeking to avoid barley and rye.**” (emphasis added)

In addition to this response taking 10 years, this response was tone deaf. It also suggests that it was not in compliance with the FDA’s Quality Resource and Development Team which stated,

“In carrying out its public health mission (reference #3) [FDA Mission Statement]⁴⁹⁶, FDA clearly understands that the American public is the primary customer of the agency’s work and the products we regulate.”⁴⁹⁷

In other words, this is no way to treat a customer at all. In the private sector, if that was a customer, they would have likely taken their business elsewhere due to what appears to be non-responsiveness and obfuscation.

I. Example 3 - May 2011 Article in Scientific American

In 2011, Dr. Diana Gitig opined in Scientific American on the labeling challenges that Americans with Celiac, NCGS and dermatitis herpetiformis face,

“As of now, FDA labeling laws do not require that the presence of gluten in foods be disclosed. These laws require only that the presence of eight major allergens be declared on food labels. Wheat is one of these allergens, but gluten is not. Manufacturers may label foods as gluten free, but such labeling is voluntary. For the millions of Americans with celiac disease, dermatitis herpetiformis, and gluten intolerance who must ensure that they are not consuming any gluten, this translates to A LOT of time spent reading labels in supermarket aisles.”⁴⁹⁸

J. Example 4 – December 6, 2016, Change.org Petition: Gluten in the Allergy Disclaimer

It is instructive for the FDA to note that in 2017, Fiona Brown started a petition on Change.org entitled “Gluten in the Allergy Disclaimer” which in part stated, “Currently, companies may put gluten in products under different names, making it hard for people with celiac disease or non-celiac gluten sensitivity to know what they can eat. Companies should be required, by law, to state gluten in the allergy disclaimer.”⁴⁹⁹

While the petition is currently closed, there were **a total of 1,048 supporters**.⁵⁰⁰ One of the commenters, Matt Maxwell from Peachtree City, Georgia stated,

“I’m signing this because the cigarettes in my pocket have a warning that they cause cancer. Gluten can do the same for us with celiac. We put warnings on every chemical

⁴⁹⁶ <http://www.fda.gov/opacom/morechoices/mission.htm>

⁴⁹⁷ <https://web.archive.org/web/20210309071904/https://www.fda.gov/media/77398/download>

⁴⁹⁸ <https://blogs.scientificamerican.com/guest-blog/when-and-why-did-everyone-stop-eating-gluten/>

⁴⁹⁹ <https://www.change.org/p/fda-gluten-in-the-allergy-disclaimer>

⁵⁰⁰ <https://www.change.org/p/fda-gluten-in-the-allergy-disclaimer>

known to man if it can hurt you in some way but not with gluten. Just because it's not an instant reaction like peanuts does to some people the medical issues are there.”⁵⁰¹

K. Example 5 – August 18, 2017, Citizen Petition from Tricia Thompson, Gluten Free Watchdog

On August 18, 2017, Tricia Thompson, Founder of Gluten Free Watchdog, filed a citizen petition which “Requests that the FDA establish a specific protocol for increased surveillance, investigation and enforcement of potential Facial Misbranding violations under the ‘Gluten-Free Labeling Rule’” (“Gluten Free Watchdog Citizen Petition”).⁵⁰²

On August 22, 2017, Dynna Bigby, Supervisory Administrative Proceedings Specialist, Division of Dockets Management, FDA/Office of the Executive Secretariat (OES), sent an acknowledgment letter to the Petitioners.⁵⁰³

According to Gluten Free Watchdog on January 14, 2018, “[t]he Petition has received overwhelming public support, with over 1,200 favorable comments received to-date. The public comments come almost entirely from individual consumers, most of whom are celiac disease patients, and many comments contain compelling personal stories.”⁵⁰⁴ ⁵⁰⁵ In addition, the Gluten Free Watchdog Citizen Petition was supported in written comments by consumer organizations: Center for Science in the Public Interest on December 20, 2017,⁵⁰⁶ the National Celiac Association on November 24, 2017,⁵⁰⁷ and Beyond Celiac on August 17, 2017.⁵⁰⁸

On February 13, 2018, Douglas A. Balentine, Ph.D., Director, Office of Nutrition, and Food Labeling, Center for Food Safety, and Applied Nutrition, wrote to the Petitioners,

“This responds to your citizen petition dated August 18, 2017, under docket number FDA-2017-P-5118 requesting that the Food and Drug Administration “take action to establish a protocol for increased surveillance, investigation and enforcement of potential Facial Misbranding violations under the ‘Gluten-Free Labeling Rule’” (78 FR 47154, August 5, 2013) codified at 21 CFR 101.91. **We are advising you, in accordance with 21 CFR 10.30(e)(2), that we have not reached a decision on your petition within the first 180 days due to competing priorities. However, be advised that your petition is currently under active evaluation by our staff.**”⁵⁰⁹ (emphasis added)

⁵⁰¹ <https://www.change.org/p/fda-gluten-in-the-allergy-disclaimer/c/701100334>

⁵⁰² Document ID: FDA-2017-P-5118-0001; Tracking Number: 1k1-8y8g-ut1b; https://downloads.regulations.gov/FDA-2017-P-5118-0001/attachment_2.pdf

⁵⁰³ FDA-2017-P-5118, https://downloads.regulations.gov/FDA-2017-P-5118-0002/attachment_2.pdf

⁵⁰⁴ Supplement to Citizen Petition by Gluten Free Watchdog, FDA-2017-P-5118, January 14, 2018

https://downloads.regulations.gov/FDA-2017-P-5118-1256/attachment_1.pdf

⁵⁰⁵ <https://www.regulations.gov/docket/FDA-2017-P-5118/comments>

⁵⁰⁶ <https://www.regulations.gov/document?5D=FDA-2017-P-5118-1156>

⁵⁰⁷ <https://www.regulations.gov/comment/FDA-2017-P-5118-1053>

⁵⁰⁸ <https://www.regulations.gov/document?D=FDA-2017-P-5118-0230>

⁵⁰⁹ https://downloads.regulations.gov/FDA-2017-P-5118-1369/attachment_2.pdf

It is unclear what the FDA's "competing priorities" were that precluded the FDA from reaching a common sense decision within the first 180 days after the filing of Gluten Free Watchdog Citizen Petition. However, it is clear that as of the date of the filing of this Citizen Petition to label Gluten as a Major Food Allergen on all packaged foods in the U.S., the FDA has not made any decisions, let alone even provided an update, to Gluten Free Watchdog's 2017 Petition since February 13, 2018.

L. Example 6 – 2020, Change.org Petition: FDA - Require Gluten to be Labeled as an Allergen!

In 2020, Galen Rydzik started this petition -- "FDA - Require gluten to be labeled as an allergen!" -- on Change.org and 1,625 people signed the petition,

"Currently, the Food Allergen Labeling and Consumer Protection Act of 2004 requires that all food containing the 8 most common allergens (milk, eggs, fish, shellfish, tree nuts, peanuts, wheat, and soybeans) be labeled as having such. **It does not, however, require that gluten be labeled as an allergen. This is extremely problematic because grains such as rye, barley, and triticale do not have to be labeled on food containers.** These grains can be found in 'ingredients' that do not specify what they are made of, such as natural flavors, modified food starch, caramel color, and artificial colors. There are many other such ingredients that are more obvious, but this can make it difficult for those who have recently discovered their allergy. Many food manufacturers will use ingredients that are cross-contaminated with barley (such as chocolate), yet they are not required to mention this on their label. In many cases, **it leaves many with Celiac Disease to guess as to whether or not they think there could be any possibility food may be unsafe...** As such, I am asking that the FDA update its guidelines to include gluten on food labels. This would take out the 'guessing game' that comes with reading food labels. This will also help to bring about a greater awareness to the public and the food industry- many with celiac disease find it difficult to dine out when food staff are ignorant of their allergies. Additionally, this lack of labeling may cause serious issues for those with Celiac Disease in the near future; the FDA recently approved substitution of some ingredients in foods that do not include the 8 major allergens due to COVID, but this does not include ingredients that are derived from other gluten containing grains or ingredients that are cross-contaminated with them."⁵¹⁰

The Change.org Web site indicates that there was an additional corresponding petition which appears to have been created under the Trump Administration White House, but that is no longer online.⁵¹¹ As of June 15, 2022, Mr. Rydzik reported that FDA never responded to his petition entitled "FDA - Require gluten to be labeled as an allergen!"⁵¹²

⁵¹⁰ <https://www.change.org/p/food-and-drug-administration-fda-require-gluten-to-be-labeled-as-an-allergen>

⁵¹¹ This page, "<https://petitions.whitehouse.gov/petition/add-gluten-list-recognized-allergens-food-labels>" just redirects to the Biden-Harris White House Web site. Additionally, this petition does not appear on this Web site, <https://trumpwhitehouse.archives.gov/>

⁵¹² Jon Bari's email communication with Galen Rydzik, June 15, 2022.

M. Example 7 – 2022, Gluten Free Labeling Rule (21 CFR 101.91) is Not Being Enforced by the FDA

As recently as February 23, 2022, the National Celiac Association, Beyond Celiac, the Society for the Study of Celiac Disease, the Gluten Intolerance Group, and Celiac Community Foundation of Northern California joined Gluten Free Watchdog in appealing to the FDA about its lack of enforcement action against manufacturers labeling products Gluten Free that list barley malt ingredients,

“We are deeply concerned that the gluten-free labeling rule (21 CFR 101.91) is not being enforced by FDA. Based on a review of FDA’s Enforcement Reports page⁵¹³ for the period from January 1, 2020 to February 16, 2022, there have been a total of three recalls for products labeled gluten-free containing undeclared barley but these products were recalled for other misbranding problems, specifically undeclared wheat or peanuts. There has not been any public FDA enforcement action for misbranded products labeled gluten-free listing a barley ingredient, namely malt, malt syrup, malt extract, or malt vinegar. This includes at least 14 products reported to FDA by Gluten Free Watchdog during this period.”⁵¹⁴

N. FDA’s Decade Long Delay to Voluntarily Label Gluten Free Products Has Become Normalized, Including Serving as Legal Justification by a Federal Judge in a Ruling About “All Natural” Food Labeling

The FDA’s 10 year delay in defining the final rule for voluntary Gluten Free labeling⁵¹⁵ has helped normalize and create a domino effect whereby the Federal government has historically underserved, marginalized, and adversely affected Celiacs with inequality.

The FDA’s decade long delay in issuing the final rule for voluntary labeling has even had pernicious ripple effects through other parts of our Federal government, including the judicial system. For example, in a Memorandum and Order from Roslynn Mauskopf, United States District Court Judge for the Eastern District of New York, Judge Mauskopf cited the FDA’s almost decade long delay to decide matters in a consolidated multi-district litigation involving purported claims that Frito-Lay North America and its parent company, PepsiCo, Inc. deceptively labeled marketed some of its products as “All Natural” when the products contained unnatural, genetically-modified organisms.

“In an analogous situation, the FDA took nine years to define the requirements a manufacturer must meet before it can label a food gluten-free. Brady Dennis, ‘Nine Years after Congress Request, FDA defines Gluten-free,’ Wash. Post, Aug. 2, 2013, available at https://www.washingtonpost.com/national/health-science/9-years-after-congress-request-fda-defines-gluten-free/2013/08/01/cfeb2c08-faef-11e2-a369-d1954abcb7e3_story.html (last visited Aug. 20, 2013). This nine-year period was in the face of a mandate from Congress to define the term gluten-free. In the Food Allergen Labeling and Consumer Protection Act, enacted into law on August 2, 2004, Congress directed the FDA to issue a rule to define and permit use of the term

⁵¹³ <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/enforcement-reports>

⁵¹⁴ <https://www.glutenfreewatchdog.org/news/lack-of-fda-enforcement-action-against-manufacturers-labeling-products-gluten-free-that-list-barley-malt-ingredients>

⁵¹⁵ <https://www.federalregister.gov/documents/2013/08/05/2013-18813/food-labeling-gluten-free-labeling-of-foods>

gluten-free. Gluten-Free Labeling of Foods, 78 Fed. Reg. 47,154, 47,156 (Aug. 5, 2013) (to be codified at 21 C.F.R. pt. 101). The agency published the final rule on August 5, 2013 in the Federal Register. *Id.* A similar deliberative, open, and considered process would likely be undertaken to address labeling of foods containing genetically modified ingredients, and there is no reason to believe that the FDA would abandon its deliberative process in order to respond to the Courts referral through a hurried, ad hoc, and closed manner.”⁵¹⁶ (emphasis added)

⁵¹⁶ Memorandum & Order, In re Frito-Lay North America, Inc. All Natural Litigation, Case 1:12-cv-04638-RRM-RLM, Document 38, Filed August 29, 2013, Roslynn R. Mauskopf, United States District Court Judge for the Eastern District of New York, https://www.govinfo.gov/content/pkg/USCOURTS-nyed-1_12-cv-04638/pdf/USCOURTS-nyed-1_12-cv-04638-1.pdf

XI. The Economics of Celiac Disease – The Consumer Financial Burden of the Medically Required Gluten Free Diet

“Back at the beginning, I sold a lot of my belongings along with receiving food stamps and WIC just to afford food, as you can’t use food banks when you have allergies. They think it’s a luxury. For us, it’s life.”

--Mother of child with food allergy and annual income <\$50K⁵¹⁷

A. Food Insecurity and the Treatment Burden: Celiacs Have Been Denied Opportunity to Participate Fully in Economic, Social & Civic Life

The food insecurity and treatment burden for Celiac Disease (i.e., constant threat of cross contact, Gluten is in 80% of all foodstuffs, and Gluten is not required to be labeled on all packaged foods in the US) is compounded by the increased cost of a “market basket” of Gluten Free products against a comparable market basket of Gluten containing products whereby research from Columbia University indicated that Gluten Free products were 183% more expensive nationwide.⁵¹⁸ For the average American family with Celiac Disease, NCGS or with any other medical needs that require a Gluten Free diet, that additional cost may represent an incredible expense, and one that can contribute to poor adherence to maintaining a strict Gluten Free diet, which in turn can cause more serious health issues. Families with low incomes, who have at least one member with Celiac Disease or NCGS, are disproportionately impacted to an even greater extent in terms of food insecurity. According to the 2019 Columbia University study, “The study market basket was based on the food and beverage portion of the USDA market basket which includes breakfast cereal, bread, milk, coffee, wine, chicken, service meals, and snacks based on national consumption data from the United States Department of Labor statistics.”⁵¹⁹

On July 26, 2022, the Washington Post reported, “Over the past 18 months, Americans have faced ongoing waves of steep price hikes as inflation hit 40-year highs.”⁵²⁰ We can personally attest to how inflation has impacted us, including with regard to the ever-increasing prices of Gluten Free foods (which already had premium prices pre-pandemic). To that end, we recently conducted our own market basket research in Philadelphia, and the Gluten Free product prices were much higher when compared to their Gluten containing products.

⁵¹⁷ <https://www.foodallergy.org/fare-consumer-journey-infographic>

⁵¹⁸ <https://www.celiacjourney.com/post/food-insecurity-in-the-context-of-celiac-disease>

⁵¹⁹ <https://celiacdiseasecenter.columbia.edu/wp-content/uploads/2019/07/2019-Persistent-Economic-Burden-of-the-Gluten-Free-Diet.pdf>

⁵²⁰ <https://www.washingtonpost.com/business/2022/07/26/inflation-causes/>

Figure 11 - Market Shopping in the Philadelphia Area as of July 10, 2022 (See Sources in Exhibit A herein)⁵²¹

Product Category	Gluten-Containing Products			Gluten Free Products		
	Standard Packaged Food	Price	Price Per Ounce	Gluten Free Packaged Food	Price	Price Per Ounce
Bread	Stroehmann King White Sandwich Bread - 22oz, 26 slices [1]	\$2.49	\$0.11	Canyon Bakehouse Gluten Free Mountain White Bread - 18oz, 15 slices [2]	\$6.79	\$0.38
Cake Mix	Pillsbury Funfetti Cake mix, 15.25 oz [3]	\$1.99	\$0.13	Pillsbury Gluten Free Funfetti Cake Mix, 17 oz [4]	\$4.79	\$0.28
Chicken Nuggets	Perdue Simply Smart chicken Nuggets, 29 oz [5]	\$11.99	\$0.41	Perdue Simply Smart Gluten Free Chicken Nuggets, 22 oz [6]	\$11.99	\$0.55
Cookies	Chips Ahoy original 13 oz [7]	\$3.99	\$0.31	Tate's Gluten Free Chocolate Chip Cookies, 7 oz [8]	\$6.69	\$0.96
Cookie Dough	Pillsbury Chocolate Chip Cookie Dough - 16oz/24ct [33]	\$3.49	\$0.15	Sweet Loren's Gluten Free Vegan Chocolate Chunk Cookie Dough - 12oz, 12ct [34]	\$6.89	\$0.57
Cornbread Mix	Krusteaz Cornbread Mix, 15 oz. [9]	\$2.59	\$0.17	Krusteaz Cornbread Mix Gluten Free, 15 oz. [10]	\$4.79	\$0.32
Fish Sticks	Gorton's Fish Sticks, 24.5 oz. [11]	\$7.49	\$0.31	Ian's Gluten Free Fish Sticks, 14 oz. [12]	\$9.99	\$0.71
Flour	King Arthur All Purpose Flour, 5 lbs [13]	\$5.39	\$0.07	King Arthur Measure for Measure Flour, 48 oz [14]	\$10.99	\$0.23
Granola Bars	Quaker Chewy chocolate chip granola bars, 6.7 oz, 8 count [15]	\$2.69	\$0.40	Made Good Granola Bars, chocolate chip, 5.1 oz. 6 count [16]	\$5.19	\$1.02
Hamburger Buns	Wonder White Hamburger Buns, 12oz, 8 buns [17]	\$2.59	\$0.22	Udi's Gluten Free Hamburger Buns, 10.4 oz, 4 buns [18]	\$4.59	\$0.44
Mac & Cheese	Kraft Macaroni & Cheese Dinner Original & Cheese Dinner, 7.25oz [19]	\$1.29	\$0.18	Kraft Gluten Free Macaroni & Cheese Original Flavor, 6.0oz [20]	\$4.39	\$0.73
Oatmeal	Quaker Oats 100% Whole Grain Old Fashioned - 18 Oz [21]	\$4.99	\$0.28	Quaker Select Starts Gluten Free Oats Quick 1-Minute - 18 Oz [22]	\$5.69	\$0.32
Pancake Mix	Bisquick original pancake mix, 40 oz. [23]	\$4.59	\$0.11	Bisquick Gluten Free Pancake Mix, 16 oz [24]	\$5.99	\$0.37
Penne Pasta	Barilla Penne Pasta, 16 oz. [25]	\$2.19	\$0.14	Barilla Penne Pasta Gluten Free, 12 oz. [26]	\$2.99	\$0.25
Pizza	Freschetta Pizza, 26.11 oz [27]	\$6.79	\$0.26	Freschetta Gluten Free pizza, 17.5 oz [28]	\$10.99	\$0.63
Pretzels	Snyders of Hanover Pretzels dipping sticks, 12 oz [29]	\$3.29	\$0.21	Snyders of Hanover, Gluten Free Pretzel Sticks, 8 oz [1]30	\$3.99	\$0.50
Rice Crispy Treats	Rice Krispie Treats, 12.4 oz, 16 count [31]	\$4.99	\$0.40	Made Good Vanilla Crispy Squares, 4.68 oz, 6 count [32]	\$4.59	\$0.98

⁵²¹ Stores shopped: Target (4000 Monument Road, Philadelphia, PA 19131) and Acme (Philadelphia/Bala Cynwyd, 121 E. City Avenue, Bala Cynwyd, PA 19004); stores are located within 1 mile of each other. Note that the citations for the products and prices can be found in Exhibit A at the end of the Comments.

Figure 12 (prices derived from Figure 11 herein)

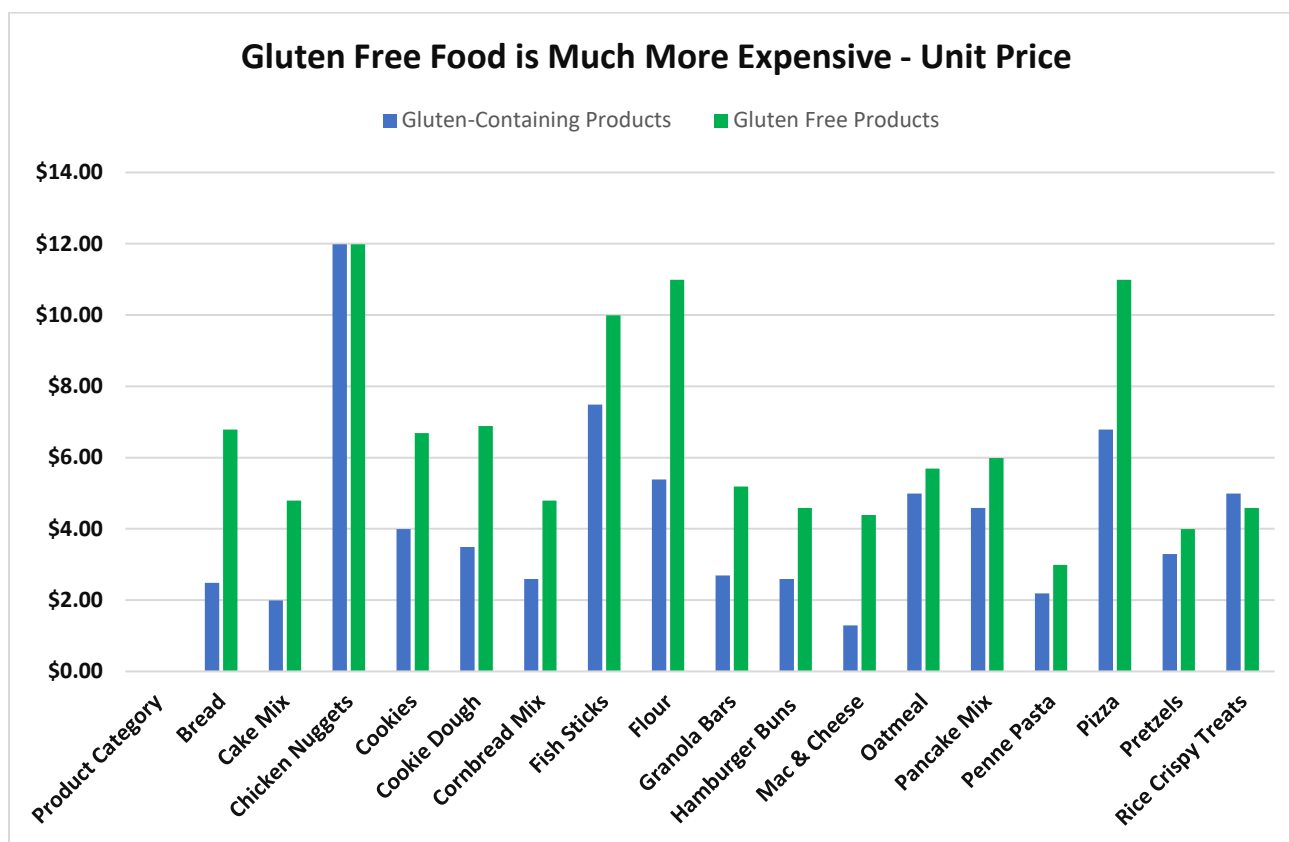
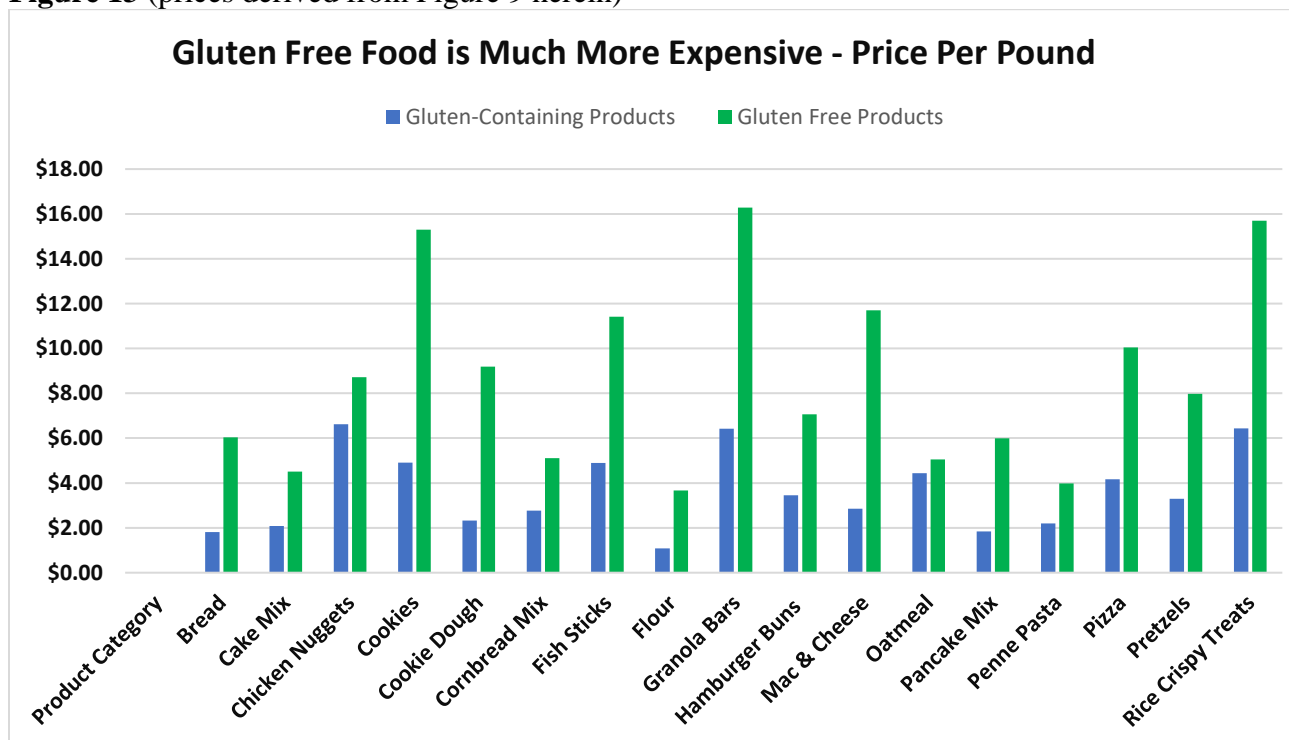


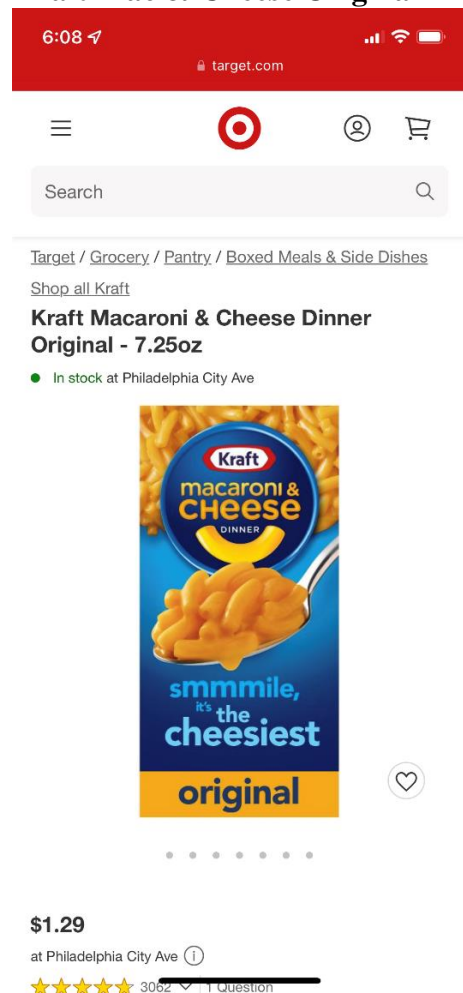
Figure 13 (prices derived from Figure 9 herein)



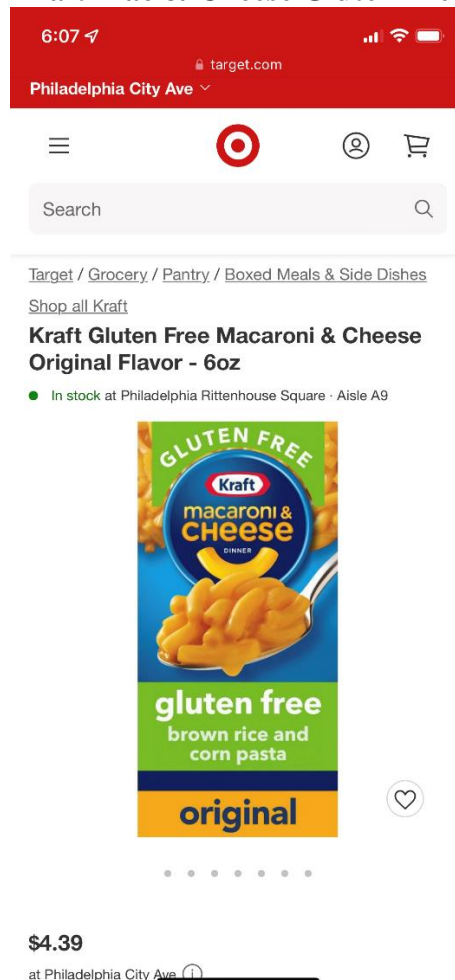
B. A Tale of Two Kraft Mac & Cheese Dinners

Kraft considers its Mac & Cheese as “comfort food.”⁵²² While we are appreciative that Kraft offers a Gluten Free version of this comfort food, we take no comfort in the fact that Kraft Macaroni & Cheese Dinner Original, 7.25oz sells for \$1.29⁵²³ (\$0.18 per ounce), whereas Kraft Gluten Free Macaroni & Cheese Original Flavor, 6.0oz sells for \$4.39⁵²⁴ (\$0.73 per ounce).

Kraft Mac & Cheese Original



Kraft Mac & Cheese Gluten Free



Some would suggest that the price disparity is because there are more ingredients used in the Gluten Free versions of food. However, in terms of ingredients in this example, the Kraft Mac & Cheese Dinner Original contains more ingredients than the Gluten Free counterpart. The Original contains “Enriched Macaroni (Wheat Flour, Durum Flour, Niacin, Ferrous Sulfate [Iron], Thiamin Mononitrate [Vitamin B1], Riboflavin [Vitamin B2], Folic Acid)”, but is replaced in the Gluten Free version with “Gluten Free Pasta (Corn Flour, Brown Rice Flour).”^{525 526}

⁵²² <https://www.cnn.com/2022/06/22/business-food/kraft-mac-and-cheese-name/index.html>

⁵²³ <https://www.target.com/p/kraft-macaroni-38-cheese-dinner-original-7-25oz/-/A-12954218>

⁵²⁴ <https://www.target.com/p/kraft-gluten-free-macaroni-38-cheese-original-flavor-6oz/-/A-79684594>

⁵²⁵ <https://www.target.com/p/kraft-macaroni-38-cheese-dinner-original-7-25oz/-/A-12954218>

⁵²⁶ <https://www.target.com/p/kraft-gluten-free-macaroni-38-cheese-original-flavor-6oz/-/A-79684594>

According to The New York Times, in a 2014 article entitled, “A Big Bet on Gluten-Free,”

“Rebecca Thompson, a marketing manager at General Mills, said relying on the data on levels of celiac and gluten sensitivity in the population to predict the staying power of consumer demand underestimated how many people were eating gluten-free products. ‘When you think about the dynamics in a household, where there are likely to be three other people eating at the same time as one person with celiac or gluten sensitivity, it’s much easier to prepare one meal for everyone.’”⁵²⁷

While it may be healthy for General Mills’ bottom line to benefit from a family of four maintaining a Gluten Free household when just one member of the family requires a Gluten Free diet, it can be quite expensive for the average American who requires a Gluten Free diet for one, let alone someone who may want to prepare one meal for everyone in the household that they can all eat together. This speaks to how costs can be multiplied throughout a household, especially for premium products such as Gluten Free foods, and moreover how for families with low incomes, they are disproportionately impacted to an even greater extent in terms of inequity and food insecurity.

According to Grocery Dive’s 2017 article, “Is gluten-free still worth the investment for retailers?”,

“Retailers have enjoyed the higher margins and intense customer loyalty that come with gluten-free. And many remain fully invested in the trend. But others see warning signs that a much-anticipated downturn could still lie ahead. At the very least, capitalizing on gluten-free demand presents a complex proposition for supermarkets one that requires both smart merchandising and consumer outreach, which seeks to meet diverging needs for the same products.”⁵²⁸

In 2009, General Mills attributed growth in multiple categories including cereals and baking products to the introduction of gluten-free products.⁵²⁹ In 2011, even when other categories were performing poorly, Gluten Free products broke the trend and still produced as General Mills noted that Gluten Free products that were introduced had good initial sales results.⁵³⁰

In their 2015 Annual Report, General Mills described their Gluten Free product offerings as an attempt to meet consumer demand: “For example, nearly 30 percent of U.S. consumers have purchased gluten-free products as recently as our fourth fiscal quarter, so we’ve increased our gluten-free cereal offerings to include varieties of granola and hot oatmeal. And starting this

⁵²⁷ Strom, Stephanie. “A Big Bet on Gluten-free.” The New York Times, 17 February 2014. <https://www.nytimes.com/2014/02/18/business/food-industry-wagers-big-on-gluten-free.html> . Accessed 26 June 2022.

⁵²⁸ <https://www.grocerydive.com/news/grocery---gluten-free-grocery-investment/535453/>

⁵²⁹ “General Mills Reports Strong Results for Fiscal 2010 First Quarter.” SEC, 23 September 2009.

<https://www.sec.gov/Archives/edgar/data/0000040704/000095012309045055/c53735exv99w1.htm>.

⁵³⁰ “General Mills Reports Fiscal 2011 First-Quarter Results.” SEC, 22 September 2011.

<https://www.sec.gov/Archives/edgar/data/0000040704/000095012310087965/c60382exv99w1.htm>.

summer, five varieties of Cheerios will be gluten free.”⁵³¹ In 2022, General Mills’ status as the third largest producer of gluten-free food in the U.S. is considered a fiscal highlight for the company.⁵³²

According to Grand View Research, some of the prominent manufacturers in the Gluten Free products are: “Conagra Brands, Inc.; The Hain Celestial Group Inc.; General Mills Inc.; Kellogg Co.; The Kraft Heinz Company; Hero AG; Barilla G. e R. Fratelli S.p.A; Seitz glutenfrei; Freedom Foods Group Limited; Ecotone.”⁵³³

The bottom line is that Gluten Free food market today is big business. According to a report by Global Market Insights Inc., the Gluten Free Food market was “estimated at USD 8.90 billion in 2020 and is projected to be valued at more than USD 17.05 billion by 2027, registering with a CAGR of 9.5% from 2021 to 2027.”⁵³⁴

C. The Premium & Lucrative Market Developed for Gluten Free Food

The Food Allergy Consumer Journey, Defining Challenges, Overcoming Obstacles, Creating a Blueprint for Food Allergen Labeling Success” conducted by McKinsey & Company, Northwestern University and Global Strategy Group for Food Allergy Research & Education (FARE) found,

“Premium buyers / They spend more

Food Allergy Consumers are premium buyers, spending five percent more on average for groceries per month than the average surveyed consumer, with 32 percent indicating they are willing to spend more on the highest quality ingredients.”⁵³⁵

As have seen herein, there is a significant premium cost associated with maintaining a Gluten Free diet.

If the labeling of Gluten was mandatory on all products, it is our belief that the number of Gluten Free food products available to those who have Celiac Disease or NCGS would greatly expand just by virtue of food products that do not contain Gluten being labeled as such. Additional research would be worthwhile to analyze this in more detail.

⁵³¹ “General Mills – 2015 Annual Report.”

https://s22.q4cdn.com/584207745/files/doc_financials/2015/annual/Gen-Mills-AR-2015a-FINAL.pdf.

⁵³² “General Mills Highlights Progress in 2022 Global Responsibility Report.” General Mills Press Releases, 19 April 2022. <https://investors.generalmills.com/press-releases/press-release-details/2022/General-Mills-Highlights-Progress-in-2022-Global-Responsibility-Report/default.aspx>.

⁵³³ “Gluten-Free Products Market Size, Share & Trends Analysis Report By Product (Bakery Products, Dairy/Dairy Alternatives), By Distribution Channel (Supermarkets & Hypermarkets, Convenience Stores), By Region, And Segment Forecasts, 2022 – 2030.” Grand View Research. <https://www.grandviewresearch.com/industry-analysis/gluten-free-products-market> .

⁵³⁴ <https://www.globenewswire.com/news-release/2022/03/01/2393849/0/en/The-Gluten-Free-Food-Market-to-exceed-USD-17-05-billion-by-2027-says-Global-Market-Insights-Inc.html>

⁵³⁵ <https://www.foodallergy.org/media/1059/download>

In the absence of required labeling, coupled with a voluntary consumer diet fad for Gluten Free foods, we believe that this has caused Gluten Free food, in part, to be much more expensive than regular food items by creating a premium or gourmet-like high-priced market segment. While allergen free foods are more expensive than their allergen containing counterparts, anecdotal evidence suggests that allergen free foods do not appear to be marked up nearly as much as Gluten Free products are compared with their Gluten containing counterparts, albeit further research is needed on these economic issues.

D. Offsetting the Cost of Gluten Free Food

While the following is likely out of the direct purview of the FDA, it is nonetheless instructive for the FDA to understand these financial implications of the Gluten Free diet.

Given the high price of Gluten Free food, there should be some financial offset to compensate individuals, families and caretakers who purchase Gluten Free food for someone who medically requires being on a Gluten Free diet. While in theory there are some tax deductions available for medical expenses associated with Gluten Free food, not many people are able to take advantage of these deductions based on the complex and cumbersome IRS filing requirements.⁵³⁶ In addition to potentially changing the tax code to allow for all Celiac patients and their families the right to deduct the incremental cost for Gluten Free food, another potential idea for example to accommodate the high cost of Gluten Free food would be for all of the associated expenses therefore to qualify as medical expenses towards meeting certain health insurance plan deductibles.

E. The Merchandising of Gluten Free Food

According to the FDA, “‘Gluten-Free’ Means What It Says -- Not long ago, gluten-free foods on the grocery shelves could be hard to find. Not so much, now.”⁵³⁷

While it may be easier to find Gluten Free food since the voluntary Gluten Free labeling final rule went into effect in August 2014, it is certainly not easy! Period. Full stop. That is a meaningful distinction with a difference. The FDA’s “not so much, now” statement suggests another example of food privilege that does not acknowledge the perpetual state of food insecurity that many Celiacs like my son can face every day with every bite in the absence of mandatory labeling.

While we understand that the FDA is not directly involved in food merchandising, it is though instructive for the FDA to consider the downstream merchandising implications and consumer behavior that flow from voluntary Gluten Free labeling and how that can contribute to consumer confusion and undermine consumer protection during the shopping experience for Gluten Free food.

In a video from Children’s National Hospital in Washington, D.C. “What does 20ppm gluten really look like?”, there is a discussion on the voluntary labeling scheme for Gluten Free products which illustrates how consumer confusion can easily arise.

⁵³⁶ “Tax deductions for gluten-free food.” National Celiac Association.

<https://nationalceliac.org/resources/tax-deductions-gluten-free-food/>

⁵³⁷ <https://www.fda.gov/consumers/consumer-updates/gluten-free-means-what-it-says>

“Voluntary labeling. Now it’s important to remember that there are thousands of products in a grocery store that are naturally gluten free or are manufactured using gluten-free ingredients that will not have a gluten-free label. **You mean that there are things that are Gluten Free that don’t say it on the package? Yes [on screen: ‘It might be a law, but labeling it is not.’], the FDA law is a voluntary rule which means that a company doesn’t have to label their product as Gluten Free unless they want to and have tested it to make sure it complies with the 20 ppm standard.** The bottom line is that you always need to check food labels. If there are any questions, contact the manufacturer directly to find out how the product is made.”⁵³⁸ (emphasis added)

According to Gluten-Free Living in June 2015,

“Many shoppers are seeking out stores with stand-alone gluten-free sections, and food retailers of all sizes are filling the need. At Sprouts, every location has a dedicated area that contains only certified-gluten-free products. ‘This is an important differentiator for people with celiac disease because it allows them to have a simpler shopping experience by focusing on this one aisle rather than having to search throughout the store for various gluten-free products,’ explains Little [Director of Nutrition, Sprouts Farmers Market].”⁵³⁹

The Food Network published “The Beginners Guide to Gluten-Free Grocery Shopping, Your primer to navigating the grocery store in search of gluten-free products”, and it speaks to some of the many challenges in food shopping depending on how merchandising of Gluten Free food is done, which can vary greatly from chain to chain and even from one store in a chain to another store within the same chain. There are also geographic variability with the availability of Gluten Free food items whereby some areas appear to have stores which stock more Gluten Free food products more than other areas.

“Ask customer service where to find gluten-free products. Sure, you could just walk up and down every aisle the best way to really get to know a supermarket, and worth the time if you regularly shop at the same store. You can also ask if there’s a natural foods section, which usually has shelves stocked with gluten-free goods. Otherwise, some stores have dedicated gluten-free aisles for fast shopping, while others blend in gluten-free products with their gluten-full counterparts.”⁵⁴⁰

In other words, there is no consistent merchandising scheme for Gluten Free foods at various retailers. For example, some retailers have a dedicated Gluten Free aisle(s) for consumer packaged foods, including for refrigerated and/or frozen items. However, in the case when there is not a dedicated Gluten Free aisle(s), coupled with the voluntary labeling scheme for Gluten, then consumers are left to go on a search through the store and read many labels, which can result in a very time consuming and costly trip to the market. According to “The Food Allergy Consumer Journey, Defining Challenges, Overcoming Obstacles, Creating a Blueprint for Food Allergen Labeling Success” conducted by McKinsey & Company, Northwestern University and Global Strategy Group, 71% of consumers “check food labels every time they shop – some for 3-

⁵³⁸ https://youtu.be/aaQhIJ_06Vw?t=190

⁵³⁹ <https://www.glutenfreeliving.com/gluten-free-foods/shopping-gluten-free/supermarkets/>

⁵⁴⁰ <https://www.foodnetwork.com/healthyeats/2016/05/the-beginners-guide-to-gluten-free-grocery-shopping>

5 minutes per product.”⁵⁴¹ In that particular scenario where there is not a dedicated Gluten Free aisle(s), it is even more important to have Gluten labeled on all food products which will reduce time spent deciphering labels and mitigate adverse health effects from accidental Gluten ingestion.

According to Gluten-Free Living,

“The level of competition among bread manufacturers - large and small - **for shelf space is fierce**, according to Scott Owen, the grocery merchandiser at Seattle-based PCC Natural Markets. He says that ultimately it’s not the brand name that dictates whether a product stays or goes -- **sales numbers dictate the fate of all products**. Sprouts assesses the sales data of gluten-free products more frequently than other store categories because of continued improvements, product selection and consumer demand, says Little.”⁵⁴² (emphasis added)

The Gluten Free Living article speaks to the financial pressures that retailers are under to maximize sales in terms of shelf space (real estate) in markets. Manufacturers are also under intense financial pressures to increase sales volume and product margins, and the Gluten Free marketplace helps them achieve these business goals. In other words, stores will regularly reallocate shelf space and pull products when certain products and segments are not performing as well as they would like.

F. Our Lived Experience with Gluten Free Food Shopping

From our personal lived experience, some of our neighborhood supermarkets previously had dedicated aisles to Gluten Free food, including for refrigerated and frozen foods. Then some of the neighborhood markets eliminated the dedicated aisles and/or refrigerator/freezer cases, reduced the amount of Gluten Free foods that they carried and interspersed the more limited array of Gluten Free products throughout the rest of the market. From personal experience, Wegman’s sets the gold standard for the variety of Gluten Free foods and the manner in which these Gluten Free food products are curated and merchandised in dedicated aisles and refrigerator/freezers. However, the closest Wegman’s to our home is about 14 miles (about a 26 minute ride by car), which is not very convenient.

Shortly after Jax first began his Celiac journey at age 5 in 2018, I realized that Celiac had been an abstract disease to us, and I was struggling with ways of sharing with friends and family how dangerous and challenging this life changing disease was. Then came the pandemic, and COVID provided experiences for all that emulated some of our lived experiences with Celiac. For example, the abstract concepts of isolation, social distancing, fear, uncertainty, scarcity, and inflation with Celiac were now being experienced by many within the context of COVID.

Let me explain. When I first studied marketing at the Wharton School as an undergraduate student at the University of Pennsylvania, I studied how consumer packaged goods companies market their products to children and display them at their eye level in the supermarket (cereals, snacks, candy, drinks, etc.). Since Jax’s 2018 Celiac diagnosis, I have often wandered through supermarkets with my wife, Leslie, and son trying to identify safe Gluten Free products and

⁵⁴¹ <https://www.foodallergy.org/fare-consumer-journey-infographic> ; and <https://www.foodallergy.org/food-allergy-consumer-journey>

⁵⁴² <https://www.glutenfreeliving.com/gluten-free-foods/shopping-gluten-free/supermarkets/>

realizing how hard this “eye candy” must be to Jax when so many of the food products that catch his eye and make him salivate are now items that he simply could not eat without getting very sick. It was then, and it is still now, heartbreaking to think how limited Jax and the 3 million other Celiacs are in the vastly limited subset of foods that they can safely eat!

I wondered how I could visually and verbally communicate this to others -- this level of food insecurity with the limited availability of safe food. When the pandemic and supply chain issues caused store shelves to be bare, I thought that this was a powerful analogy. When pandemic prices for almost all groceries soared including for cereal and baked goods; dairy; meat, poultry and eggs; as well as fruits and vegetables, I thought that the analogy became even more compelling.⁵⁴³ The empty shelves with a very limited supply of certain food items, coupled with soaring prices, symbolized to me a Celiac’s everyday reality with the limited amount of available, affordable and safe food in any given market.

G. The Voluntary Gluten Free Diet Fad May Fade

I have also worried that as with all fad diets, the voluntary Gluten Free diet preference will fade over time, the number of voluntarily labeled Gluten Free products will contract, and the amount of shelf space allocated at retailers for voluntarily labeled Gluten Free products will contract. As discussed, we have already seen dedicated Gluten Free shelves, sections and aisles disappear in chain retailers like Acme and Giant in the Philadelphia area. The negative feedback cycle could also likely also cause less voluntarily labeled Gluten Free products to be introduced into market and ultimately, there will be fewer products voluntarily labeled Gluten Free.

According to “Against the Grain” as published by the New Yorker,

“Fad dieting is nothing new in America; it’s what we do instead of eating balanced, nutritiously wholesome meals. Scarsdale, Atkins, South Beach, Zone, flexitarian, pescatarian, and paleo have all been awarded their fifteen minutes of fame and then shoved aside for the next great diet. They are rarely effective for long. **Some nutrition specialists say that the current preoccupation with gluten-free products reminds them of the national obsession with removing fats from foods in the late nineteen-eighties.** ‘Low-fat’ foods are often packed with sugar and calories to make up for the lack of fat. The same is true of many products that are advertised as ‘gluten-free’.”⁵⁴⁴
(emphasis added)

While many market analysts continue to predict a growing Gluten Free market, some believe that the Gluten Free market could collapse based on the enormous disconnect in numbers between those who need a Gluten Free diet due to medical reasons and those who are choosing to pursue

⁵⁴³ According to the Washington Post on August 10, 2022, “Food costs have climbed every month this year. Groceries are 12.2 percent higher now than they were last summer the biggest year-over-year spike in 43 years, federal data shows. Fruits and vegetables cost 8 percent more, staples such as bread and cereal have jumped 14 percent, and butter and margarine are up a whopping 26 percent.” See <https://www.washingtonpost.com/business/2022/08/10/food-prices-rising/> and “Increased food prices led by rise in cost of grains and dairy, Percent change in consumer price index since July 2021, seasonally adjusted”, <https://www.washingtonpost.com/business/2022/inflation-charts/>

⁵⁴⁴ <http://www.newyorker.com/magazine/2014/11/03/grain>

a Gluten Free diet without any medical need simply because Gluten Free may be perceived as healthier.

However, some studies also show that although the Gluten Free market has continued to expand, more and more people are growing skeptical that eating Gluten Free has health benefits for those who are not allergic or intolerant to Gluten. According to Grocery Dive's 2017 article, "Is gluten-free still worth the investment for retailers?",

"Considering that gluten-free products are typically pricier than their conventional counterparts, why are they purchased by people who don't need them? Gluten-free skepticism is trickling down to the consumer level. A 2015 Mintel study found that 47% of consumers think gluten-free is a fad, up from 31% who said the same two years earlier."⁵⁴⁵

According to economist Dr. Vikram Mansharamani⁵⁴⁶ in an article published in Fortune entitled "We're in a gluten-free bubble that is about to burst,"

"Gluten-free. It's among the hottest trends in food today. It competes with non-GMO, local and organic for mindshare among today's health-conscious, price-insensitive, and trend-following foodies, yuppies, and self-anointed amateur nutritionists... Like financial bubbles, the herd behavior identified by such popular attention is never sustainable. Here's the big disconnect that captures the essence of the problem: less than 1 percent of the population has celiac disease, approximately 6 percent are gluten intolerant, and ... drum roll please ... almost 30 percent of American adults are trying to avoid gluten. One of the main reasons consumers avoid gluten is they feel it's healthier. It's generally not."⁵⁴⁷

"The blunt reality is that many gluten-free foods are not healthier for the 93 percent of the population that doesn't have celiac disease or gluten sensitivity. Consider that a Glutino Original New York Style Bagel has 26 percent more calories, 250 percent more fat, 43 percent more sodium, 50 percent less fiber and double the sugar of a Thomas Plain Bagel. Further, because many gluten-free products utilize rice flour, they are also at risk of containing higher levels of arsenic than desirable or healthy."⁵⁴⁸

⁵⁴⁵ Wells, Jeff. "Is Gluten-Free Still Worth the Investment for Retailers?" Grocery Dive, 15 February 2017. <https://www.grocerydive.com/news/grocery---gluten-free-grocery-investment/535453/>. Accessed 26 June 2022.

⁵⁴⁶ "Dr. Vikram Mansharamani is a global trend-watcher who shows people how to anticipate the future, manage risk, and spot opportunities. He is the author of the recently-released *THINK FOR YOURSELF: Restoring Common Sense in an Age of Experts and Artificial Intelligence* and *BOOMBUSTOLOGY: Spotting Financial Bubbles Before They Burst*. He has been a frequent commentator on issues driving disruption in the global business environment. Vikram's ideas and writings have also appeared in *Bloomberg*, *Fortune*, *Forbes*, *The New York Times* and a long list of other publications. LinkedIn twice listed him as their #1 Top Voice for Money, Finance and Global Economics and *Worth* has profiled him as one of the 100 most powerful people in global finance. Millions of readers have enjoyed his unique multi-lens approach to connecting seemingly irrelevant dots." Source: <http://www.mansharamani.com/>

⁵⁴⁷ Mansharamani, Vikram. "We're in a gluten-free bubble that is about to burst." *Fortune*, 5 May 2015. <https://fortune.com/2015/05/05/gluten-free-foods/>

⁵⁴⁸ <https://www.consumerreports.org/cro/magazine/2012/11/arsenic-in-your-food/index.htm>

And then there's the cost. The Glutino bagel I just described costs 74 percent more than the Thomas bagel. Nabisco's Gluten-Free Rice Thins cost 84 percent more per cracker than Nabisco's Multigrain Wheat Thins. And when it gets to baking products, the costs are even higher. Betty Crocker's gluten-free brownie mix is more than 3 times the cost per serving of Duncan Hines regular mix.

While economic logic might lead you to conclude that higher prices would lead to lower demand, you'd be wrong. In a classic indicator of bubble dynamics, higher prices have been met with higher demand."⁵⁴⁹

On July 12, 2015, the BBC published an article entitled "The great gluten-free diet fad" which stated: "A report on the US gluten-free market by Mintel values it at almost \$9bn, because 'the health halo surrounding the gluten-free category continues to drive general consumer interest'. The singer Miley Cyrus encapsulated the mood in a tweet: 'Gluten is crappppp anyway!'"^{550,551}

According to Glutagen, an Australian biopharmaceutical company focused on providing clinically-relevant and scientific evidence-based complementary medicines to support the health and wellbeing of individuals with gluten-related issues,

"Disappointingly, the researchers [on the cost of a Gluten Free diet] found an ongoing increase in overall GF product prices and an ongoing drop in GF product availability. They noted that other studies had found similar patterns in several countries, including the UK, Austria and Chile."⁵⁵²

H. The 2022 Baby Formula Shortage is Instructive to Understand Food Insecurity and Market Forces in the Context of Food for Those Who Have Special Dietary Requirements

Prior to the pandemic, when I shared with others my concern that the demand for Gluten Free foods may contract one day because a new fad diet will replace the voluntary elected Gluten Free diet, which could then in turn cause the amount of Gluten Free products available to contract, which could then result cause prices to spike even higher, I felt that my concerns were dismissed as if I was an alarmist. Then the pandemic hit, and unimaginable realities set in on a multitude of fronts. This became even more focused during the baby formula shortage of 2022.

According to the Washington Post,

"The nationwide formula shortage has focused on the plight of infants. But some older children and adults depend on specially formulated powders, much of it made by Abbott, to compensate for a variety of ailments, from malformed bowels and allergies to problems processing nutrients like protein. While most healthy babies can switch easily

⁵⁴⁹ Mansharamani, Vikram. "We're in a gluten-free bubble that is about to burst." Fortune, 5 May 2015. <https://fortune.com/2015/05/05/gluten-free-foods/>

⁵⁵⁰ <https://twitter.com/MileyCyrus/status/189209905415192578>

⁵⁵¹ <https://www.bbc.com/news/magazine-33486177>

⁵⁵² <https://glutagen.com/the-cost-of-a-gluten-free-diet/#:~>

from brand to brand, for these people, a poorly chosen substitute can either taste intolerable or prompt dehydration, seizures and even death.”⁵⁵³

In Congressional testimony on May 25, 2022 from Dr. Robert Califf, FDA Commissioner, Frank Yiannas, MPH, Deputy Commissioner, Food Policy and Response, and Dr. Susan Mayne, Director, Center for Food Safety and Applied Nutrition on Formula Safety And Supply: Protecting The Health Of America’s Babies,

“Chair DeGette, Ranking Member Griffith, and members of the Subcommittee, thank you for inviting us here today to testify before you on supply disruptions in infant formula. We have all seen the images of empty store shelves and heard the stories of parents of kids unable to find the food their children need to survive. This situation is unacceptable. The staff at the U.S. Food and Drug Administration (FDA or the Agency) feel this not just as public servants whose job it is to ensure that these critical products are safe and nutritious, but also as parents and grandparents. Our top priority now is addressing the dire need for infant formula in the U.S. market, and our teams are working night and day to help make that happen.”⁵⁵⁴

In that same vein as it pertains to the only available treatment for Celiac Disease -- a strict Gluten Free diet for life -- we are appealing to the FDA, as public servants, parents and grandparents, for help! We rely on you, the FDA, to ensure critical food products are safe and nutritious, but also readily available. For Celiacs, in addition to products being on store shelves, products must not contain Gluten. There are many products that are free from Gluten but just not labeled since there is no mandatory labeling scheme.

It is illustrative to let the baby formula fiasco be a wake-up call so we do not repeat this again, including with the market for specialized foods such as Gluten Free foods potentially disappearing from market shelves. From the baby formula crisis, we have learned that markets for specialized foods (i.e., “specially formulated powders, much of it made by Abbott, to compensate for a variety of ailments, from malformed bowels and allergies to problems processing nutrients like protein”) can be disrupted by macro-economic, micro-economic, supply chain, operational shocks, etc.

Before the baby formula recall, “Abbott controlled 40% of the infant formula market, including Similac, but the market share of other companies such as Reckitt Benckiser Group PLC (RKT.L) has grown since then.”⁵⁵⁵ While there may not be one company that controls 40% of the Gluten

⁵⁵³ <https://www.washingtonpost.com/health/2022/06/03/baby-formula-shortage-metabolic-disorder/>

⁵⁵⁴ TESTIMONY OF ROBERT M. CALIFF, M.D. COMMISSIONER OF FOOD AND DRUGS FRANK YIANNAS, M.P.H. DEPUTY COMMISSIONER, FOOD POLICY AND RESPONSE SUSAN T. MAYNE, PH.D. DIRECTOR, CENTER FOR FOOD SAFETY AND APPLIED NUTRITION FOOD AND DRUG ADMINISTRATION DEPARTMENT OF HEALTH AND HUMAN SERVICES BEFORE THE SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS COMMITTEE ON ENERGY AND COMMERCE U.S. HOUSE OF REPRESENTATIVES Formula Safety And Supply: Protecting The Health Of Americas Babies, May 25, 2022, <https://www.fda.gov/media/158739/download>

⁵⁵⁵ <https://www.reuters.com/business/healthcare-pharmaceuticals/abbott-raises-2022-profit-forecast-2022-07-20/#:~>

Free market today, there are some large multinational food companies (as previously discussed herein) involved in producing Gluten Free food.

In the event that tastes change and the market for Gluten Free food declines among those consumers who voluntarily elect to pay these premiums (i.e., the “Gluten Free tax”) and consume Gluten Free food, then the supply of available safe Gluten Free food will also likely shrink. Moreover, in the absence of required labeling of Gluten on all packaged foods, and in the event that the Gluten Free lifestyle market declines or fades away and people without a medical necessity to eat Gluten Free food declines, the Celiac community will be left with even fewer choices to eat adequately and safely. This will likely force prices even higher on a more limited array of Gluten Free foods. This is another reason that Gluten should be labeled on all packaged foods in the U.S.

XII. The Only Available Treatment for Celiac -- Gluten Free Food – Must Be Viewed as a Human Right

“Where, after all, do universal human rights begin? In small places, close to home -- so close and so small that they cannot be seen on any maps of the world. [...] Unless these rights have meaning there, they have little meaning anywhere. Without concerted citizen action to uphold them close to home, we shall look in vain for progress in the larger world.”

-- Eleanor Roosevelt, Chair of the United Nations Human Rights Commission

A. Overview

In the seminal work by Juliana Nadal at the Department of Nutrition, Food Quality and Nutrition at the Federal University of Parana in Brazil, “The principle of human right to adequate food and Celiac Disease,” Nadal linked the Human Right to Adequate Food with Celiac Disease,

“By understanding food as a basic human right, it is less complex to understand the fact that the absence of foods that address this particular need, such as that of Celiac individuals, represents a concrete case that this group of people are having, constantly, their rights – to adequate nutrition – violated and, in turn, they are in a state of food and nutrition insecurity.”⁵⁵⁶

Yvonne Vissing Ph.D. and Christopher Moore-Vissing advanced Nadal’s discussion and provided thought leadership in their article, “Going Gluten Free as a Human Rights Issue”,

“Because Celiac Disease can be considered the most common food intolerance in the world, it is one that both individuals and social structures need to address as a mainstream issue. **From how laws and consumer protections are designed at the macro level, to how food is made available and prepared at the micro level, rights of people with Celiac Disease hang in limbo.** Some places and people are very attentive to their rights protections while others are not. Nadal contextualizes food and nutrition insecurity that afflicts individuals with Celiac Disease with specific regard to the principle of the Human Right to Adequate Food (HRAF).” (emphasis added)

“When you’ve got Celiac Disease and people aren’t attentive to making sure you can eat gluten-free foods that are safely prepared and not contaminated, you can end up very sick in the short-run. The short-term effects may include symptoms such as gastrointestinal upset, migraines, fuzzy brain, sweats, and general malaise. As a fundamental right, what one eats should ensure people’s access to a healthy, dignified and full life. People who have been “glutened” do not feel dignified as they writhe in pain, wrestle with fears of embarrassment, or modify their lifestyle and social schedules to accommodate the illness. In the long-run, if someone is continually exposed to gluten in foods, a variety of serious preventable health conditions may result. Unlike a peanut allergy that can directly kill you, exposure to gluten may result in morbidity and early mortality for people in an indirect fashion. Adhering to a gluten-free diet is of paramount importance to avoid health problems such as compromising one’s weight and pubertal development, fertility,

⁵⁵⁶ Nadal, J., Ferreria, S.M., et al. “The principle of human right to adequate food and celiac disease: advancements and challenges.” 2013, <https://www.e-publicacoes.uerj.br/index.php/demetra/article/download/5991/7652> , Demetra; 2013; 8(3); 411-423

bone mineral density, and deficiencies of micro and macronutrients, not to mention the increased risk of developing malignancies, especially in the gastrointestinal system. Because the health effects of ingesting gluten for someone with Celiac Disease are less visible to those who don't experience them, they [Celiac patients] have been easier to ignore. Thanks to vocal advocates who now know that going gluten-free can save their lives, it is obvious that the lack of attention to making sure people can eat safely is a violation of their rights.”⁵⁵⁷

B. Universal Declaration of Human Rights (UDHR)

For the estimated 75 million people worldwide with Celiac Disease, the Universal Declaration of Human Rights expressly and directly links “health and well-being” with adequate food.

In 1948, the United Nations Universal Declaration of Human Rights (UDHR)⁵⁵⁸ was established as a foundational document in the history of human rights. “Drafted by representatives with different legal and cultural backgrounds from all regions of the world, the Declaration was proclaimed by the United Nations General Assembly in Paris on 10 December 1948 by General Assembly resolution 217 A (III) as a common standard of achievements for all peoples and all nations. It sets out, for the first time, fundamental human rights to be universally protected.” Article 25 of the Universal Declaration of Human Rights states,

“1. Everyone has the right to a standard of living adequate for the **health and well-being** of himself and of his family, **including food**, clothing, housing and medical care and necessary social services, and **the right to security in the event of** unemployment, **sickness, disability**, widowhood, old age or other lack of livelihood in circumstances beyond his control.

2. Motherhood and **childhood are entitled to special care and assistance**...”⁵⁵⁹
(emphasis added)

According to the UN's “Plain Language Version” of the UDHR, Article 25.1 means,

“You have the right to have whatever you need so that you and your family: **do not fall ill; do not go hungry**...”⁵⁶⁰ (emphasis added)

Even though the Universal Declaration of Human Rights holds the Guinness World Record as the most translated document in the world (into more than 500 languages as of 2019⁵⁶¹), there are many people who are still unaware of their basic rights as human beings, including public servants in the United States government and even those in the Celiac community with the Right to Adequate Food.

⁵⁵⁷ Vissing, Yvonne; Moore-Vissing, Christopher, “Going Gluten Free as a Human Rights Issue.” Journal of Gluten Sensitivity, Summer 2016 Issue, 11 July, 2016.

<https://www.celiac.com/articles.html/going-gluten-free-as-a-human-rights-issue-r3798/>

⁵⁵⁸ <https://www.un.org/en/conferences/human-rights>

⁵⁵⁹ <https://www.un.org/en/about-us/universal-declaration-of-human-rights>

⁵⁶⁰ <https://www.ohchr.org/sites/default/files/Documents/Publications/ABCannexesen.pdf>

⁵⁶¹ “Most Translated Document,” Guinness World Records. 2009.

<https://www.guinnessworldrecords.com/world-records/most-translated-document>

C. The United Nations Convention on the Rights of the Child

The United Nations Convention on the Rights of the Child expressly and directly links the importance of “combating (pediatric) disease and malnutrition, including within the framework of primary health care... through the provision of adequate nutritious foods”. Additionally, the Convention on the Rights of the Child addresses “the right of the child to the enjoyment of the highest attainable standard of health and to facilities for the treatment of illness and rehabilitation of health. States Parties shall strive to ensure that no child is deprived of his or her right of access to such health care services.”⁵⁶² Additionally, the concept that “childhood is entitled to special care and assistance” as enshrined in the United Nations Universal Declaration of Human Rights is expressly included in the Preamble to the “Convention on the Rights of the Child” that went into effect on September 2, 1990.

According to Article 3.1.,

“In all actions concerning children, whether undertaken by public or private social welfare institutions, courts of law, administrative authorities or legislative bodies, **the best interests of the child shall be a primary consideration.**”⁵⁶³ (emphasis added)

According to Article 24.1,

“States Parties recognize the right of the child to the enjoyment of the highest attainable standard of health and to facilities for the treatment of illness and rehabilitation of health. States Parties shall strive to ensure that no child is deprived of his or her right of access to such health care services.”⁵⁶⁴

According to Article 24.2,

“(b) To ensure the provision of necessary medical assistance and health care to all children with emphasis on the development of primary health care;
(c) **To combat disease and malnutrition**, including within the framework of primary health care, through, inter alia, the application of readily available technology **and through the provision of adequate nutritious foods** and clean drinking-water, taking into consideration the dangers and risks of environmental pollution;...
(e) To ensure that all segments of society, in particular parents and children, **are informed, have access to education and are supported in the use of basic knowledge of child health and nutrition**, the advantages of breastfeeding, hygiene and environmental sanitation and the prevention of accidents;” (emphasis added)⁵⁶⁵

The bottom line is that to address how the Celiac community has been historically underserved by the Federal government, including but not limited to the underfunding of Celiac Disease research, the voluntary labeling of Gluten and the disqualification from service in the military, the “legislative bodies” such as the U.S. Congress and the “administrative authorities” such as FDA, NIH, CDC, and DoD should use the Convention on the Rights of the Child as a guiding

⁵⁶² “Convention on the Rights of the Child.” United Nations. 20 November 1989.

<https://www.ohchr.org/sites/default/files/Documents/ProfessionalInterest/crc.pdf>

⁵⁶³ <https://www.ohchr.org/sites/default/files/Documents/ProfessionalInterest/crc.pdf>

⁵⁶⁴ <https://www.ohchr.org/sites/default/files/Documents/ProfessionalInterest/crc.pdf>

⁵⁶⁵ “Convention on the Rights of the Child.” United Nations. 20 November 1989.

<https://www.ohchr.org/sites/default/files/Documents/ProfessionalInterest/crc.pdf>

principle in the allocation of resources for the protection of consumers (labeling of Gluten) and funding of research: “the best interests of the child shall be a primary consideration.”

To those ends, the legislative and administrative bodies should “recognize the right of the child to the enjoyment of the highest attainable standard of health” whereby “[t]o combat disease and malnutrition, including within the framework of primary health care,... through the provision of adequate nutritious foods” is foundational. In addition to research for a treatment and a cure, appropriations from the USDA and DoE should be allocated “[t]o ensure that all segments of society, in particular parents and children, are informed, have access to education and are supported in the use of basic knowledge of child health and nutrition” with respect to Celiac Disease.

D. The Right to Adequate Food, United Nations Office of the Commissioner for Human Rights

According to the United Nations Office of the Commissioner for Human Rights “The Right to Adequate Food, Fact Sheet No. 34,”

“Combating hunger and malnutrition is more than a moral duty or a policy choice; in many countries, it is a legally binding human rights obligation. The right to food is recognized in the 1948 Universal Declaration of Human Rights as part of the right to an adequate standard of living, and is enshrined in the 1966 International Covenant on Economic, Social and Cultural Rights.”⁵⁶⁶ (emphasis added)

As a preliminary matter, it is important to note that one of the common misconceptions about the Right to Food. According to the United Nations,

“The right to food is NOT the same as a right to be fed. Many assume that the right to food means that Governments have to hand out free food to anyone who needs it. They conclude that this would not be feasible or might cause dependency. This is a misunderstanding. The right to food is not a right to be fed, but primarily the right to feed oneself in dignity. Individuals are expected to meet their own needs, through their own efforts and using their own resources.”⁵⁶⁷ (emphasis added)

What is the Right to Food?

According to the United Nations, food must be available, accessible and adequate:

- “Availability requires on the one hand that food should be available from natural resources either through the production of food, by cultivating land or animal husbandry, or through other ways of obtaining food, such as fishing, hunting or gathering. On the other hand, it means that food should be available for sale in markets and shops.”
- **“Accessibility requires economic and physical access to food to be guaranteed.** Economic accessibility means that food must be affordable. Individuals should be able to afford food for an adequate diet without compromising on any other basic needs, such as school fees, medicines or rent.”
- **“Adequacy means that the food must satisfy dietary needs,** taking into account the individual’s age, living conditions, **health**, occupation, sex, etc. For example, if children’s

⁵⁶⁶ “The Right to Adequate Food, Fact Sheet No. 34.” United Nations.

<https://www.ohchr.org/Documents/Publications/FactSheet34en.pdf>

⁵⁶⁷ “The Right to Adequate Food, Fact Sheet No. 34.” United Nations.

<https://www.ohchr.org/Documents/Publications/FactSheet34en.pdf>

food does not contain the nutrients necessary for their physical and mental development, it is not adequate. Food that is energy-dense and low-nutrient, which can contribute to obesity and other illnesses, could be another example of inadequate food. **Food should be safe for human consumption and free from adverse substances, such as contaminants** from industrial or agricultural processes, including residues from pesticides, hormones or veterinary drugs. Adequate food should also be culturally acceptable. For example, aid containing food that is religious or cultural taboo for the recipients **or inconsistent with their eating habits** would not be culturally acceptable.”⁵⁶⁸ (emphasis added)

According to Vissing and Moore-Vissing in their article entitled, “Going Gluten Free as a Human Rights Issue,”

“The issue of gluten contamination contributes to a constant situation of food and nutritional insecurity to holders of this special dietary need. The celiac diet must be completely gluten-free, which allows people to have a life relatively free of major pathological complications. Maintaining a totally gluten-free diet is not an easy task because the violation of the diet may occur voluntarily or involuntarily, and **range from incorrect information on food labels to the gluten** contamination of processed products. Difficulties in the availability and access to food without gluten violates the principle of the [United Nations] human right to adequate food. **The condition of being a Celiac individual exposes one to permanent food and nutrition insecurity, which could cause loss of quality of life, socialization, and health of the individual, both in the short and long term.**”⁵⁶⁹ (emphasis added)

E. The Link Between the Right to Adequate Food and Other Human Rights

According to the United Nations Office of the Commissioner for Human Rights “The Right to Adequate Food, Fact Sheet No. 34,”

“Human rights are interdependent, indivisible and interrelated. This means that violating the right to [adequate] food may impair the enjoyment of other human rights, such as the right to health, education or life, and vice versa.”⁵⁷⁰

For example, according to the United Nations, the Right to Adequate Food is interdependent and interrelated with these rights:

- **“The right to health. Nutrition is a component of both the right to health and the right to food... When a child is suffering from diarrheal disease but denied access to medical treatment, it cannot enjoy an adequate nutritional status even if he or she has access to food.”**
- **“The right to life.** When people are not able to feed themselves and face the risk of death by starvation, **malnutrition or resulting illnesses, their right to life would also be at stake.**”

⁵⁶⁸ “The Right to Adequate Food, Fact Sheet No. 34.” United Nations.

<https://www.ohchr.org/Documents/Publications/FactSheet34en.pdf>

⁵⁶⁹ Vissing, Yvonne; Moore-Vissing, Christopher, “Going Gluten Free as a Human Rights Issue.” Journal of Gluten Sensitivity, Summer 2016 Issue, 11 July, 2016.

<https://www.celiac.com/articles.html/going-gluten-free-as-a-human-rights-issue-r3798/>

⁵⁷⁰ “The Right to Adequate Food, Fact Sheet No. 34.” United Nations.

<https://www.ohchr.org/sites/default/files/Documents/Publications/FactSheet34en.pdf>

- “**The right to information.** Information is crucial for the right to food. It enables individuals to know about food and nutrition, markets and the allocation of resources. It strengthens people’s participation and free consumer choice. **Protecting and promoting the right to seek, receive and impart information thus facilitates the enjoyment of the right to food.**”⁵⁷¹ (emphasis added)

⁵⁷¹ <https://www.ohchr.org/sites/default/files/Documents/Publications/FactSheet34en.pdf>

XIII. IgE-Mediated Food Allergies to Gluten from Rye, Barley & Oats

“A crust eaten in peace is better than a banquet partaken in anxiety.”

-- Aesop

A. Cautionary Tale on the Dangers of Gluten Causing Anaphylactic Shock

In December 2020, Hillary Carter, food allergy mom and advocate (FARE Board of Governors), bravely shared her family’s harrowing ordeal. “When ‘Safe’ Food Isn’t... Our Applegate Anaphylaxis Story” is about her young son Grayson who ate chicken nuggets that were labeled Gluten Free and casein-free, in addition to free of the Top 8 allergens per the manufacturer’s Web site. However, after eating the nuggets, Grayson went into anaphylactic shock because the product somehow contained traces of Gluten.⁵⁷²

Thankfully, after receiving four doses of epinephrine and enduring an overnight hospital stay, Grayson recovered. However, one cannot help but think that this happened to a young boy from eating a product that was labeled Gluten Free that somehow got cross contaminated with Gluten. While this is a cautionary tale over the real risks of cross contamination, it is also an important cautionary tale of why mandatory labeling of Gluten must now be enacted because of all of the places where Gluten can hide in plain sight and be dangerous to those who consume even trace amounts of Gluten, regardless of what biologically happens in the body (i.e., IgE-Mediated and Non-IgE-Mediated food allergies).

While Celiacs face potentially life-threatening and severe adverse health effects that can arise through Gluten ingestion including by way of example and not limitation: anemia, cancer, heart disease, immunological scarring, intestinal damage, malnutrition, there are also those people like Grayson who are allergic to Grains Containing Gluten and can suffer a severe IgE-Mediated allergic reaction from even a trace ingestion of Gluten, including from Rye, Barley and Oats.

B. Rye Allergy – IgE Mediated

The Web site of the Institute of Agriculture and Natural Resources, Food Allergy Research and Resource Program (“FARRP”) at the University of Nebraska-Lincoln links to the University of Manchester for additional information on cereals and grains including Rye.⁵⁷³

According to the University of Manchester:

“Rye is specifically used in rye bread and crisp breads. Rye can substitute for wheat in many foods.”

“Individuals with wheat allergy often react to closely related cereals like barley and rye, less frequently to the more distant relative, oats.”⁵⁷⁴

According to ThermoFisher’s Allergen Encyclopedia that was reviewed by Dr. Fabio Lachetti, Senior Medical Manager at ThermoFisher Scientific,⁵⁷⁵

⁵⁷² <https://www.hillarytollecarter.com/post/when-safe-food-isn-t-our-applegate-anaphylaxis-story>

⁵⁷³ <https://farrp.unl.edu/informallcerealsgrains>

⁵⁷⁴ <http://research.bmh.manchester.ac.uk/informall/allergenic-food/?FoodId=48>

⁵⁷⁵ <https://www.linkedin.com/in/iachetti/>

“Allergens from rye show profound cross-reactivity with other cereal grains like wheat, barley, and limited cross-reactivity with oat and even potato extracts... Sensitized individuals are advised to avoid rye flour in diet and strict labeling laws to label gluten-containing cereals have been established in various countries.”⁵⁷⁶

“Ingestion of rye can trigger food allergy symptoms in the gut and skin and may cause anaphylaxis (5).⁵⁷⁷ Anaphylaxis following the ingestion of rye has been documented. A case of a 61-year old woman without any history of drug allergy, suffering from rye-dependent exercise-induced anaphylaxis upon ingestion of toasted rye bread, has been reported. The woman developed generalized erythema, dizziness, hypotension, and facial angioedema after a 30-minute walk, one-hour post-ingestion of rye (24).⁵⁷⁸ A 32-year old Japanese baker with a history of ARC presented with anaphylactic symptoms including urticaria in the upper body, facial swelling, dyspnea, and angioedema on eyelids after consumption of bread containing 50% rye flour (23). Similarly, another study demonstrated a case of a 38-year old male baker with a history of urticaria on arms after exposure to rye flour (21).^{579,580}

“Baur et al. (1998) studied the frequency of work-related asthma in 89 bakers from the Bochum area (Group A). They summarized the data from a previous study involving 104 bakers (Group B) filing compensation claims for the baker's asthma. The study involved a control group with 43 healthy people of the same area who did not work in the bakeries. They found that 34% of the subjects from Group A, 50% from Group B, and only 10% of the Control group were positive for rye flour in IgE determination tests (11).⁵⁸¹ A study on 24 Spanish employees (92% males) from the baking industry with a history of baker's asthma showed that 71% of the workers were positive for rye flour in skin prick tests (SPTs), and 67% showed positive IgE to rye flour (12).^{582,583}

“A cross-sectional study was performed across 31 bakeries involving 517 workers across supermarket stores in South Africa to study the asthma phenotypes in these workers exposed to flour dust in the bakery. It was found that about 33% of workers documented work-related asthma due to rye flour specifically. However, these workers handled only a

⁵⁷⁶ <https://www.thermofisher.com/diagnostic-education/hcp/us/en/resource-center/allergen-encyclopedia/whole-allergens.html?key=f5#>

⁵⁷⁷ Rizzello C.G. DAM, Coda R. et al. Use of selected sourdough lactic acid bacteria to hydrolyze wheat and rye proteins responsible for cereal allergy. *Eur Food Res Technol.* 2006;223:40511.

⁵⁷⁸ Garcia-Menaya JM CG, Cordobes-Duan, Mahecha AC, Bobadilla-Gonzalez P. Rye-dependent exercise-induced anaphylaxis. *Ann Allergy Asthma Immunol* 2016;117(5):566-8.

⁵⁷⁹ Ehrlich R. PR. Bakers asthma with a predominant clinical response to rye flour. *American Journal of Industrial Medicine* 2005;48:153-5.

⁵⁸⁰ <https://www.thermofisher.com/diagnostic-education/hcp/us/en/resource-center/allergen-encyclopedia/whole-allergens.html?>

⁵⁸¹ Baur X DP, Sander - Bakers asthma: Still among the most frequent occupational respiratory disorders. *J Allergy Clin Immunol.* 1998;102:98497.

⁵⁸² Quirce S. F-NM, Escudero C., Cuesta J., de Las Heras M., Sastre J. . Bronchial responsiveness to bakery-derived allergens is strongly dependent on specific skin sensitivity. *Allergy* 2006;61(10):1202-8.

⁵⁸³ <https://www.thermofisher.com/diagnostic-education/hcp/us/en/resource-center/allergen-encyclopedia/whole-allergens.html?>

small proportion of products made up of rye flour (13).⁵⁸⁴ A study from a Korean allergy clinical center involving 5340 patients with different allergic diseases demonstrated the IgE sensitization rate and cross-reactivity to different home-made agricultural products and observed that rye grain sensitization rate was 9.5% (14).⁵⁸⁵ Allergy to rye has also been reported in Japan and other western countries (15).^{586,587}

C. Barley Allergy – IgE Mediated

The FARRP Web site at the University of Nebraska-Lincoln links to the University of Manchester for additional information on cereals and grains including Barley.⁵⁸⁸ According to the University of Manchester:

“Barley is used to make beer. It is also found in bread, soups, stews and museli [alternatively spelled Muesli in the U.S.].”⁵⁸⁹

“Individuals with wheat allergy often react to closely related cereals like barley and rye, less frequently to the more distant relative, oats.”⁵⁹⁰

According to ThermoFisher’s Allergen Encyclopedia that was reviewed by Dr. Fabio Lachetti, Senior Medical Manager at ThermoFisher Scientific,⁵⁹¹

“The majority of case reports about barley allergy have focused on adult patients with respiratory allergy known as baker’s asthma induced by barley flour, or with allergy from beer containing barley. Two cases of barley allergy have been reported in children who displayed severe anaphylactic reactions. However, few studies have evaluated barley allergy in relation to the level of barley-specific IgE and, to date, the prevalence of barley allergy has not been evaluated in a population-based study (3).”^{592,593}

⁵⁸⁴ Baatjies R LA, Sander I et al. Determinants of asthma phenotypes in supermarket bakery workers. *EurRespir J*. 2009;34:82533.

⁵⁸⁵ Yoon S.H. KYM, Kim S.H., Suh C.H., Nahm D.H., Park H.S. The sensitization rate and cross-reactivity to homemade agricultural products in adult allergy patients. *Korean J Asthma Allergy Clin Immunol*. 2005;25(4):269-75.

⁵⁸⁶ Gangal S.V. MBK. Food allergy-how much of a problem really is this in India? *Journal of Scientific and Industrial Research* 2003;62:755-65.

⁵⁸⁷ <https://www.thermofisher.com/diagnostic-education/hcp/us/en/resource-center/allergen-encyclopedia/whole-allergens.html?>

⁵⁸⁸ <https://farrp.unl.edu/informallcerealsgrains>

⁵⁸⁹ <http://research.bmh.manchester.ac.uk/informall/allergenic-food/?FoodId=63>

⁵⁹⁰ <http://research.bmh.manchester.ac.uk/informall/allergenic-food/?FoodId=48>

⁵⁹¹ <https://www.linkedin.com/in/iachetti/>

⁵⁹² Lee E, Jeong K, Lee J, Jeon SA, Park B, Lee H, et al. Clinical and Laboratory Findings of Barley Allergy in Korean Children: a Single Hospital Based Retrospective Study. *J Korean Med Sci*. 2020;35(3):e23.

⁵⁹³ <https://www.thermofisher.com/diagnostic-education/hcp/us/en/resource-center/allergen-encyclopedia/whole-allergens.html?key=f6>

“Barley cross-reactivity has been demonstrated to wheat, rye, oats and Job’s tears (also known as adlay) (3⁵⁹⁴, 16⁵⁹⁵). A case report from a patient with clinically defined beer and Rosaceae allergy had serum which cross-reacted with a 10 kDa protein from apple and peach (likely LTPs, but unknown at the time) and LTP from peach peel, carrot and broccoli (Asero et al, 2001). The barley 10 kDa was likely to be the classic LTP, also known as Hor v 14 (11)⁵⁹⁶.⁵⁹⁷

“One large-scale, multi-center case study in Korean children and adolescents showed that barley was the cause of 0.2% of immediate-type food allergy. A study including 42 Korean children (20 with clinically defined barley allergy and 22 atopic controls) demonstrated that levels of barley IgE were significantly higher in the allergic group vs the control group. After ingestion of barley in the allergic group, symptoms were mostly cutaneous (90.0%) or respiratory (40.0%), with anaphylaxis being observed in 35.0% (3).^{598,599}

On September 5, 2023, The New York Times reported about a Barley allergy,

“Erica Kem, who graduated from the University of Virginia in May, has a long list of allergies: tree nuts, seafood, peanuts, coconut, dairy, eggs, wheat, barley, sesame, beef, mustard and tomatoes. The last four weren’t addressed in the allergen-free dining hall.

The staff offered to make her custom meals, but required several hours’ notice, and with her busy schedule, she couldn’t always predict when she would eat. She couldn’t decide on the spur of the moment to socialize with her friends at the dining hall without examining the menu first.

“I would have to look ahead and be like: ‘Would I actually like it? Is it worth potential contamination?’” she said. If her parents, who live a two-hour drive away, hadn’t regularly brought her home-cooked food, she would have struggled to feed herself, she said.”⁶⁰⁰ (emphasis added)

⁵⁹⁴ Lee E, Jeong K, Lee J, Jeon SA, Park B, Lee H, et al. Clinical and Laboratory Findings of Barley Allergy in Korean Children: a Single Hospital Based Retrospective Study. J Korean Med Sci. 2020;35(3):e23.

⁵⁹⁵ Srisuwatchari W, Piboonpocanun S, Wangthan U, Jirapongsananuruk O, Visitsunthorn N, Pacharn P. Clinical and in vitro cross-reactivity of cereal grains in children with IgE-mediated wheat allergy. Allergol Immunopathol (Madr). 2020;48(6):589-96.

⁵⁹⁶ Navarro L, Lazo L, Pineda P, Labrador-Horrillo M, Roger A, Basaga. Anaphylaxis Induced by Beer. J Invest Allergol Clin Immunol. 2021;31(4):334-6.

⁵⁹⁷ <https://www.thermofisher.com/diagnostic-education/hcp/us/en/resource-center/allergen-encyclopedia/whole-allergens.html?key=f6>

⁵⁹⁸ Lee E, Jeong K, Lee J, Jeon SA, Park B, Lee H, et al. Clinical and Laboratory Findings of Barley Allergy in Korean Children: a Single Hospital Based Retrospective Study. J Korean Med Sci. 2020;35(3):e23.

⁵⁹⁹ <https://www.thermofisher.com/diagnostic-education/hcp/us/en/resource-center/allergen-encyclopedia/whole-allergens.html?key=f6>

⁶⁰⁰ The New Reality for College Dining Halls: Dozens of Dietary Restrictions, The New York Times," Priya Krishna, September 5, 2023, <https://www.nytimes.com/2023/09/05/dining/college-dining-halls-allergies-restrictions.html?>

D. Oat Allergy – IgE-Mediated

The FARRP Web site at the University of Nebraska-Lincoln links to the University of Manchester for additional information on cereals and grains including Oats.⁶⁰¹ Oats are used to make porridge and a wide variety of cakes and biscuits. According to the University of Manchester: “Oats are also found in muesli or granola. Beer can be made from oats.”⁶⁰²

According to ThermoFisher’s Allergen Encyclopedia that was reviewed by Dr. Magnus Borres, Professor of Pediatrics, Uppsala University & Medical Director ThermoFisher Scientific,⁶⁰³

“Oats are small cereal grains rich in fiber and antioxidants and possess various health benefits. It belongs to the genus *Avena*. Oats are used as cereal, fodder, hay, straw beds, grains, etc. They are more popularly consumed in Europe and are a source of food allergy. Ingestion of oat cereal or inhalation of oat flour has been reported to cause allergic reactions in sensitive individuals.

Clinically, oat allergies are reported to cause Oral Allergy Syndrome (OAS), anaphylaxis, gastro-intestinal symptoms, skin reactions, and respiratory symptoms such as rhinitis, rhino-conjunctivitis, and asthma in sensitized individuals. Children with atopic dermatitis constitute a risk group of developing epicutaneous sensitization to oats and subsequently acute allergies on using oat-containing cosmetics.

Allergens in oats haven’t yet been characterized but various studies have shown different IgE-binding proteins from oats. Cross-reactivity between gliadins from wheat and hordeins in barley, avenins from oats, coixins in Jobs tears, and secalins from rye has been observed. Additionally, cross-reactivity has been demonstrated between rice, millets, oats, and grass pollen.

Avoidance of oats is suggested as a preventative strategy against the allergic reaction caused by oat.”⁶⁰⁴

In terms of the Epidemiology and worldwide distribution, ThermoFisher stated:

“A cross-sectional study with 365 allergic Honduran children (age ranging from 1 to 18 years) showed positive skin prick test (SPT) for oats in 3% (11 out of 365) participants.”⁶⁰⁵

Worm et al. (2006) extracted a random sample of 13,300 Germans out of which 408 self-reported the prevalence of atopic dermatitis (AD). AD was confirmed in 146 individuals out of which 111 were clinically examined and 28 were diagnosed with active eczema

⁶⁰¹ <https://farrp.unl.edu/informallcerealsgrains>

⁶⁰² <http://research.bmh.manchester.ac.uk/informall/allergenic-food/?FoodId=35>

⁶⁰³ https://scholar.google.co.uk/citations?user=_ZOrQwQAAAAJ&hl=en

⁶⁰⁴ <https://www.thermofisher.com/diagnostic-education/hcp/us/en/resource-center/allergen-encyclopedia/whole-allergens.html?key=f7>

⁶⁰⁵ Gonzales-Gonzalez VA, Diaz AM, Fernandez K, Rivera MF. Prevalence of food allergens sensitization and food allergies in a group of allergic Honduran children. *Allergy Asthma Clin Immunol.* 2018;14:23.

lesions. Among them, 14.8% had a positive skin prick test (SPT) to oatmeal and barley flour.⁶⁰⁶

Boussault et al. (2007) conducted an extensive study on oat sensitization in children with AD in France. The study showed that out of 302 children, 98 (32.5%) were sensitized to oat and among them, 19.2% (58/302) were positive to oat in SPT and 14.6% (44/302) in Atopy patch test (APT).⁶⁰⁷

A study evaluated the prevalence of oat allergy in children diagnosed to have wheat allergy in Maryland, USA. Out of 185 wheat allergic patients, 10% reacted to oat extracts.^{608,609}

“Oats have been found to be linked with the cases of oral allergy symptoms.⁶¹⁰ Oat-related food allergies may be induced through the gastrointestinal (GI) tract and skin.⁶¹¹ Contact allergy to oat protein present in moisturizers has also been reported.⁶¹² Anaphylaxis associated with oat allergy has also been reported in a few studies^{613 614 615,616}

⁶⁰⁶ Worm M, Forschner K, Lee HH, Roehr CC, Edenharter G, Niggemann B, et al. Frequency of atopic dermatitis and relevance of food allergy in adults in Germany. *Acta Derm Venereol.* 2006;86(2):119-22.

⁶⁰⁷ Boussault P, Leaute-Labreze C, Saubusse E, Maurice-Tison S, Perromat M, Roul S, et al. Oat sensitization in children with atopic dermatitis: prevalence, risks and associated factors. *Allergy.* 2007;62(11):1251-6.

⁶⁰⁸ Keet C, Matsui E, Dhillon G, Lenehan P, Wood R. Barley and oat allergy in children with wheat allergy. *Journal of Allergy and Clinical Immunology.* 2009;123(2):S110.

⁶⁰⁹ <https://www.thermofisher.com/diagnostic-education/hcp/us/en/resource-center/allergen-encyclopedia/whole-allergens.html?key=f7>

⁶¹⁰ Skypala JJ. Food-Induced Anaphylaxis: Role of Hidden Allergens and Cofactors. *Front Immunol.* 2019;10:673.

⁶¹¹ Ototake Y, Inomata N, Sano S, Takahashi S, Aihara M. A case of an anaphylactic reaction due to oats in granola. *Allergol Int.* 2015;64(4):386-7.

⁶¹² Boussault P, Leaute-Labreze C, Saubusse E, Maurice-Tison S, Perromat M, Roul S, et al. Oat sensitization in children with atopic dermatitis: prevalence, risks and associated factors. *Allergy.* 2007;62(11):1251-6.

⁶¹³ Ototake Y, Inomata N, Sano S, Takahashi S, Aihara M. A case of an anaphylactic reaction due to oats in granola. *Allergol Int.* 2015;64(4):386-7.

⁶¹⁴ Tomas-Perez M, Iglesias-Souto FJ, Bartolome B. Oat Allergy: Report on 2 Cases. *J Investig Allergol Clin Immunol.* 2020;30(3):199-201.

⁶¹⁵ Prados-Casta, Pi-Saavedra M, Leguisamo-Milla S, Pastor C, Cuesta P, Bartolom. Anaphylaxis Due to Oat Ingestion. *Journal of investigational allergology & clinical immunology.* 2016;26(1):68.

⁶¹⁶ <https://www.thermofisher.com/diagnostic-education/hcp/us/en/resource-center/allergen-encyclopedia/whole-allergens.html?key=f7>

XIV. Economic Impact - Cost Estimates with Naming Gluten as A Major Food Allergen

**“Food is national security. Food is economy.
It is employment, energy, history. Food is everything.”**
-- Chef José Andrés, founder of World Central Kitchen

“Eating is an agricultural act.”
-- Wendell Berry

A. Overview

To assess any potential economic impact from the requested action with the labeling of Gluten, it is instructive to revisit that the 2021 FAO/WHO Expert Consultation (which recommended that Gluten be labeled) was comprised of 20 (twenty) “scientists, regulators, physicians, clinicians and risk managers from academia, government and the food industry were selected to participate in the first meeting of the FAO/WHO Expert Consultation on Risk assessment of Food Allergens.”⁶¹⁷ These global experts found that Gluten should be labeled on all packaged foods. In addition to the FDA’s Dr. Lauren Jackson and Dr. Stefano Luccioli, there were other experts from the United States including:

- Dr. Joseph Baumert, Professor and Director of the Food Allergy Research and Resource Program (FARRP), Department of Food Science and Technology at the University of Nebraska-Lincoln;⁶¹⁸
- Dr. Stephen Taylor, Professor and Founding Director (Retired) of the Food Allergy Research and Resource Program (FARRP), Department of Food Science and Technology at the University of Nebraska-Lincoln.⁶¹⁹ Dr. Taylor was also one of six scientists who served on the Ad Hoc Panel on Food Allergens met in Geneva, Switzerland in February 1999 to provide advice to the Joint FAO/WHO Expert Committee on Food Additives about criteria for labelling food allergens. Their treatise was memorialized in the 1999 FAO/WHO Expert Consultation; also referred to as the “1999 Codex Criteria”.⁶²⁰

See Section IV. in this Citizen Petition, “Labeling of Gluten as a Major Food Allergen Comports with Criteria & Conclusions from International Food Safety Authorities & Experts, Including from the FDA.”

B. Labeling Gluten on Packaged Foods is Commensurate with Existing Global Operations

Given that Gluten is required to be labeled on packaged foods in 87 countries worldwide, many of the multinational consumer-packaged food manufacturers already label Gluten on their products sold in those 87 other countries. As such, labeling Gluten in the United States would be commensurate with their existing global operations and best practices.

C. Congressional Budget Office – FASTER Act Benchmark, Sesame Allergen

It is instructive to look at the Congressional Budget Office (“CBO”) Cost Estimate for H.R. 2117 (which was the predecessor Bill to the FASTER Act which required the labeling of Sesame) dated November 20, 2020. The CBO’s Cost Estimate for H.R. 2117, including for the Federal

⁶¹⁷ <http://www.fao.org/3/cb4653en/cb4653en.pdf>

⁶¹⁸ <https://farrp.unl.edu/fss/joe-baumert>

⁶¹⁹ <https://farrp.unl.edu/fss/staylor>

⁶²⁰ <https://apps.who.int/iris/handle/10665/42378>

government and private sector, with labeling Sesame may be notably similar to the cost estimates involved in naming Gluten as a Major Food Allergen.

“H.R. 2117 also would add sesame to the definition of major allergens, would permit the Secretary of Health and Human Services to add food ingredients to that definition, and would require FDA to add a section to a report that the agency produces under current law. Using information from FDA, CBO expects the agency would require, on average, the equivalent of three additional full-time employees in each fiscal year from 2021-2025 to implement regulations and guidance that add sesame as a major food allergen and to evaluate whether new ingredients should be added to the list of major allergens. CBO estimates the new staffing and related expenses would cost about \$5 million over the 2021-2025 period.

H.R. 2117 would impose a private-sector mandate as defined in the Unfunded Mandates Reform Act (UMRA)⁶²¹ by requiring manufacturers of food products containing sesame to include additional information on the products label. **Because the mandate would require a minor change to existing labels, CBO estimates that the cost of the mandate would not exceed the annual private-sector threshold established in UMRA (\$168 million in 2020, adjusted annually for inflation).**”⁶²² (emphasis added)

D. Food Safety Magazine – Sesame Allergen Benchmark

It is also instructive to read the following as reported in Food Safety Magazine on June 29, 2021,

“For most manufacturers, **the addition of sesame or any other ingredient to the major food allergen list will not present much of a logistical challenge.** It is likely that manufacturers are already listing other ingredients in compliance with the Federal Food, Drug, and Cosmetic Act and will only need to modify the labels to include sesame and any other ingredient that may be added to the major food allergens list.”⁶²³ (emphasis added)

E. U.S. Farm Income: Leading Crops

We are pro farm and pro farmer. We believe in the initiative to “keep America growing” for farmers and children with Celiac. That said, we anticipate that some may argue that the requested action in this Citizen Petition will hurt farmers, but we have not seen any evidence to suggest that being pro-labeling of Gluten and pro farming are mutually exclusive with one another. To the contrary, we believe that any arguments that say farming could be hurt by labeling Gluten would be a red herring.

In evaluating the public health importance of the requested action in this Citizen Petition to label Barley, Rye and Oats as Major Food Allergens, it is also instructive to read what the Washington Post reported on May 6, 2022 about Wheat,

⁶²¹ <https://www.cbo.gov/publication/51335>

⁶²² <https://www.cbo.gov/system/files/2020-11/hr2117.pdf>

⁶²³ Matayoshi, Kelly; Lopez, Maryjo. The FASTER Act: What Companies Need to Know about the New Food Allergy Law. Food Safety Magazine, June 29, 2021. Last Accessed: November 16, 2022. <https://www.food-safety.com/articles/7223-the-faster-act-what-companies-need-to-know-about-the-new-food-allergy-law>

“Wheat is a valuable global commodity, both symbol and sustenance. In 2009, after a spike in prices, a [U.S.] Senate subcommittee proclaimed wheat ‘even more central to modern civilization than oil.’⁶²⁴ Bread is a measure of stability or instability. And that’s what makes it such a powerful propaganda tool. ‘Wheat,’ as one agriculture economist wrote during the panic of 2010, ‘is all about fear.’⁶²⁵ The real danger is not a global wheat shortage; it’s a fear-driven panic that pushes up prices and cuts off the truly hungry.”⁶²⁶

Notwithstanding Wheat’s importance to the U.S. and global economies, Wheat has been required to be labeled in the U.S. since FALCPA was enacted. Wheat has also been required to be labeled following the 1999 Codex Criteria, and today Gluten Containing Grains (including Wheat, Barley, Rye and Oats) are required to be labeled on all food products sold in more than 85 other countries today.

As it pertains to Barley, Rye and Oats, it is also instructive to view those commodities in the context of 2022 U.S. farm income generated by leading crops. In other words, the required labeling of Wheat has not hurt Wheat’s value, including with U.S. farm income. Therefore the evidence suggests that the requested required labeling of Barley, Rye and Oats in the U.S., just like it is already done in 85 other countries, will not adversely impact the value or U.S. farm income generated from those Gluten Containing Grains.

Figure 14 - 2022 U.S. Farm Income: Leading Crops⁶²⁷

Crops	U.S. Farm Income
Corn	\$88,573,921,000
Soybeans	\$62,374,502,000
Fruits and nuts	\$26,548,625,000
Vegetables and melons	\$22,401,148,000
Wheat	\$13,461,763,000
Hay	\$9,821,279,000
Cotton	\$8,906,913,000
Rice	\$3,346,959,000
Peanuts	\$1,523,138,000
Barley	\$918,748,000
Oats	\$199,003,000
Rye	\$108,822,000

To paraphrase the words of agriculture economist Bob Utterback, Gluten Containing Grains are “all about fear” to the Celiac community since even eating a crumb of Gluten Containing Grains is like eating poison! To that end, we have a right to know whether all food products sold in the U.S. have Gluten Containing Grains, and the way to accomplish that is through labeling Gluten

⁶²⁴ <https://www.hsgac.senate.gov/wp-content/uploads/imo/media/doc/REPORTExcessiveSpeculationintheWheatMarketwoexhibitschartsJune2409.pdf?attempt=2>

⁶²⁵ <https://www.agweb.com/opinion/wheat-panic-mode>

⁶²⁶ <https://www.washingtonpost.com/outlook/2022/05/06/wheat-weapon-putin-ukraine/>

⁶²⁷ USDA, Economic Research Service, <https://data.ers.usda.gov/reports.aspx?ID=17845>, Last Accessed on September 9, 2023.

as a Major Food Allergen on all packaged foods in the U.S., just like it is in more than 85 other countries worldwide.

To reiterate the brave words of my 10-year-old son Jax,

“Eating without fear is our hope! Food insecurity happens every day for Celiacs because of the constant threat of cross contact with Gluten, 80% of foods have Gluten in them, the high price of Gluten Free food, the limited availability of Gluten Free food, and moreover Gluten is not required to be labeled on packaged foods in the US like it is in Canada and across Europe.”

F. U.S. Food Industry Trade Associations

On August 17, 2022, Kailee Tkacz Buller of Alexandria, President & CEO, Institute of Shortening and Edible Oils, submitted comments to the FDA’s Draft Guidance on behalf of the following national trade associations including: American Bakers Association, American Frozen Food Institute, Consumer Brands Association, Corn Refiners Association, FMI-The Food Industry Association, International Dairy Foods Association, International Fresh Produce Association, Institute of Shortening and Edible Oils, National Confectioners Association, National Fisheries Institute, National Pasta Association, National Seasoning Manufacturers Association, Refrigerated Foods Association and the Association for Dressings & Sauces. The comments stated:

“We support the goal of providing consumers with food allergies with critical information about the presence of allergens. Overall, we appreciate that FDA’s general draft framework follows the criteria of evidence of IgE-mediation, prevalence, potency and severity which were also the agreed upon criteria of the ad hoc FAO/WHO joint expert consultation on food allergen risk assessment.”⁶²⁸

First, it is great that these 14 national trade organizations “support the goal of providing consumers with food allergies with critical information about the presence of allergens.”

Second, it is also great that these 14 national trade organizations support the “criteria of the ad hoc FAO/WHO joint expert consultation on food allergen risk assessment” from the 2021 FAO/WHO Expert Consultation.

That said, it is important to unpack the rest of the statement from the 14 national trade organizations regarding “criteria of evidence of IgE-mediation, prevalence, potency and severity.”

To be clear, the 2021 FAO/WHO Expert Consultation which included experts from the FDA and FAARP⁶²⁹ “determined that only foods or ingredients that cause immune-mediated

⁶²⁸ https://downloads.regulations.gov/FDA-2021-N-0553-1937/attachment_1.pdf

⁶²⁹ In the comments from the 14 national trade organizations, they stated “As FDA proceeds, we encourage the agency to continue to use the food and beverage industry as a resource and engage with experts in the food allergen space such as Food Allergy Research & Education (FARE), Food Allergy Research and Resource Program (FAARP), and the Asthma and Allergy Foundation of America (AAFA) to inform its work.” It is instructive to note that there were not

hypersensitivities **such as IgE-mediated food allergies and coeliac⁶³⁰ [Celiac] disease should be included on the list of foods and ingredients included in section 4.2.1.4 of the GSLPF [General Standard for the Labelling of Prepacked Foods],”⁶³¹ and that the GSLPF list includes Gluten.** (emphasis added) See Citizen Petition Exhibit 2.

The 2021 FAO/WHO Expert Consultation “identified prevalence of the immune-mediated hypersensitivity to a specific food, severity (i.e. proportion of severe objective reactions to a food/ingredient *such as anaphylaxis*), and the potency of food/ingredient (i.e. the amount of the food/ingredient required to cause objective symptoms) as the three key criteria that should be used to establish the priority allergen list.”⁶³² (emphasis added)

The 2021 FAO/WHO Expert Consultation criteria did not require the evidence of IgE-mediation. Rather it was the FDA’s Draft Guidance which required the evidence of IgE-mediation, which we felt was very biased and not supported by a science-based process, including the prevalence, potency and severity criteria set forth in the 2021 FAO/WHO Expert Consultation.

It is imperative that the criteria and findings of the 2021 FAO/WHO Expert Consultation are clear and not conflated as the same criteria set forth in the FDA’s Draft Guidance. See Section IV. in this Citizen Petition entitled, “FDA’s Draft Guidance Illustrates Bias Against Celiac Disease.”

any Celiac Disease focused advocacy organizations and experts suggested by the 14 national trade organizations in their comments.

⁶³⁰ “Coeliac” is the Greek spelling of Celiac which is used in some parts of the world.

⁶³¹ <http://www.fao.org/3/cb4653en/cb4653en.pdf>

⁶³² <http://www.fao.org/3/cb4653en/cb4653en.pdf>

XV. Certification

“Precedent is a poor reason for decisions. It calcifies the status quo without a compelling rationale. It doesn’t matter how long a tradition has stood. If the old way is wrong, it should be challenged and changed.

Progress lies in improving the future, not defending the past.”⁶³³

-- Adam Grant, Professor at the Wharton School of the University of Pennsylvania

The undersigned certify that, to their best knowledge and belief, this petition includes all information and views on which the petitioner relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.



Jonathan H. Bari, individually, on behalf of my son, Jax Bari, and Celiac Journey
Celiac Journey
226 W. Rittenhouse Square, Suite 2115A
Philadelphia, PA 19103
215.880.4595
jon@jonbari.com

/s/

Leslie S. Bari individually, and on behalf of my son, Jax Bari, and @GlutenFreeFinds_pa
@GlutenFreeFinds_pa

/s/

Jax Bari
Penn Valley, PA

/s/

Lexi Bari
Penn Valley, PA

⁶³³ <https://www.instagram.com/p/CjS8o9GuyA4/>

XVI. Key References

**“Oh, beautiful for spacious skies,
For amber waves of grain,
For purple mountain majesties
Above the fruited plain!
America! America!
God shed his grace on thee,
And crown thy good with brotherhood
From sea to shining sea.”**
-- Katharine Lee Bates

Exhibit 1

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Exhibit 4

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Exhibit 5

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Note: When Food is Poison was written by Ms. Derr when she was a student at Harvard Law School, under the supervision of Lecturer on Law Peter Barton Hutt, Partner at Covington &

Burling in Washington, D.C., for Harvard Law School's Winter 2005 Food and Drug Law course. Mr. Hutt was also former Chief Counsel to the FDA from 1971-1975. When Food is Poison won First Place in the 2005 H. Thomas Austern Memorial Writing Competition (long papers) sponsored by the Food and Drug Law Institute.

Exhibit 6

Bari Consulting Group, Celiac Journey and Gluten Free Finds, "Sharing Our Lived Experience with Celiac Disease - Comments on 'Evaluating the Public Health Importance of Food Allergens Other Than the Major Food Allergens Listed in the Federal Food, Drug, and Cosmetic Act: Guidance for FDA Staff and Stakeholders -- Draft Guidance,' August 16, 2022." FDA Comment ID: FDA-2021-N-0553-1584, FDA Tracking Number l6w-qe9m-4tjy, August 16, 2022. Cover Letter from Bari Consulting Group, Celiac Journey and Gluten Free Finds to Susan Mayne, Ph.D., Director, Center for Food Safety and Applied Nutrition, U.S. Food and Drug Administration and Frank Yiannas, Deputy Commissioner for Food Policy and Response, U.S. Food and Drug Administration.

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Exhibit 7

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